Records processed under FOIA Request #2016-6384; Released by CDRH on 08-29-2016.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

FEB 27 1989

Ms. Karen Viskochil
Official Correspondent
R & D Systems, Inc.
614 McKinley Place, N.E.
Minneapolis, MN 55413

Re: K890749
Trade Name: CBC-Tech™ Hematology Control/Multiple
Regulatory Class: II
Dated: February 10, 1989
Received: February 13, 1989

Dear Ms. Viskochil:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments. You may, therefore, market the device, subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Performance Standards) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under the Radiation Control for Health and Safety Act of 1968, or other Federal Laws or Regulations.

This letter immediately will allow you to begin marketing your device as described. An FDA finding of substantial equivalence of your device to a pre-amendments device results in a classification for your device and permits your device to proceed to the market, but it does not mean that FDA approves your device. Therefore, you may not promote or in anyway represent your device or its labeling as being approved by FDA. If you desire specific advice on the labeling for your device please contact the Division of Compliance Operations, Regulatory Guidance Branch (HFZ-323) at (301) 427-8040. Other general information on your responsibilities under the Act, may be obtained from the Division of Small Manufacturers Assistance at their toll free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,

Jerome A. Donlon, MD PhD

Jerome A. Donlon, M.D., Ph.D.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Memorandum

Date 2-22-89

From REVIEWER(S) - NAME(S) Larry J. Brindza

Subject 510(k) NOTIFICATION K890749

To THE RECORD

It is my recommendation that the subject 510(k) Notification:

✓ (A) Is substantially equivalent to marketed devices.

____ (B) Requires premarket approval. NOT substantially equivalent to marketed devices.

____ (C) Requires more data.

____ (D) Is an incomplete submission. (See Submission Sheet).

Additional Comments:

R & D's CBC-TECH is a 3 level, multiparameter quality control material intended for use on the Technicon H1 automated differential cell counter. This control was modified by changing the formulation of the RBC base. The control is equivalent to the previous version of CBC-TECH and also to similar controls marketed by Coulter, Technicon, and Streck. The device is regulated under "Hematology Quality Control Mixture" (864.8625).

The submitter requests:

✓ No Confidentiality

____ Confidentiality for 90 days

____ Continued Confidentiality exceeding 90 days

Class Code w/Panel: II JPK-81

REVIEW: HB 2-22-89 (BRANCH CHIEF) FEB 22 1989 (DATE)

FINAL REVIEW: Jerome A Donlon MD PhD 2-24-89 (DIVISION DIRECTOR) (DATE)

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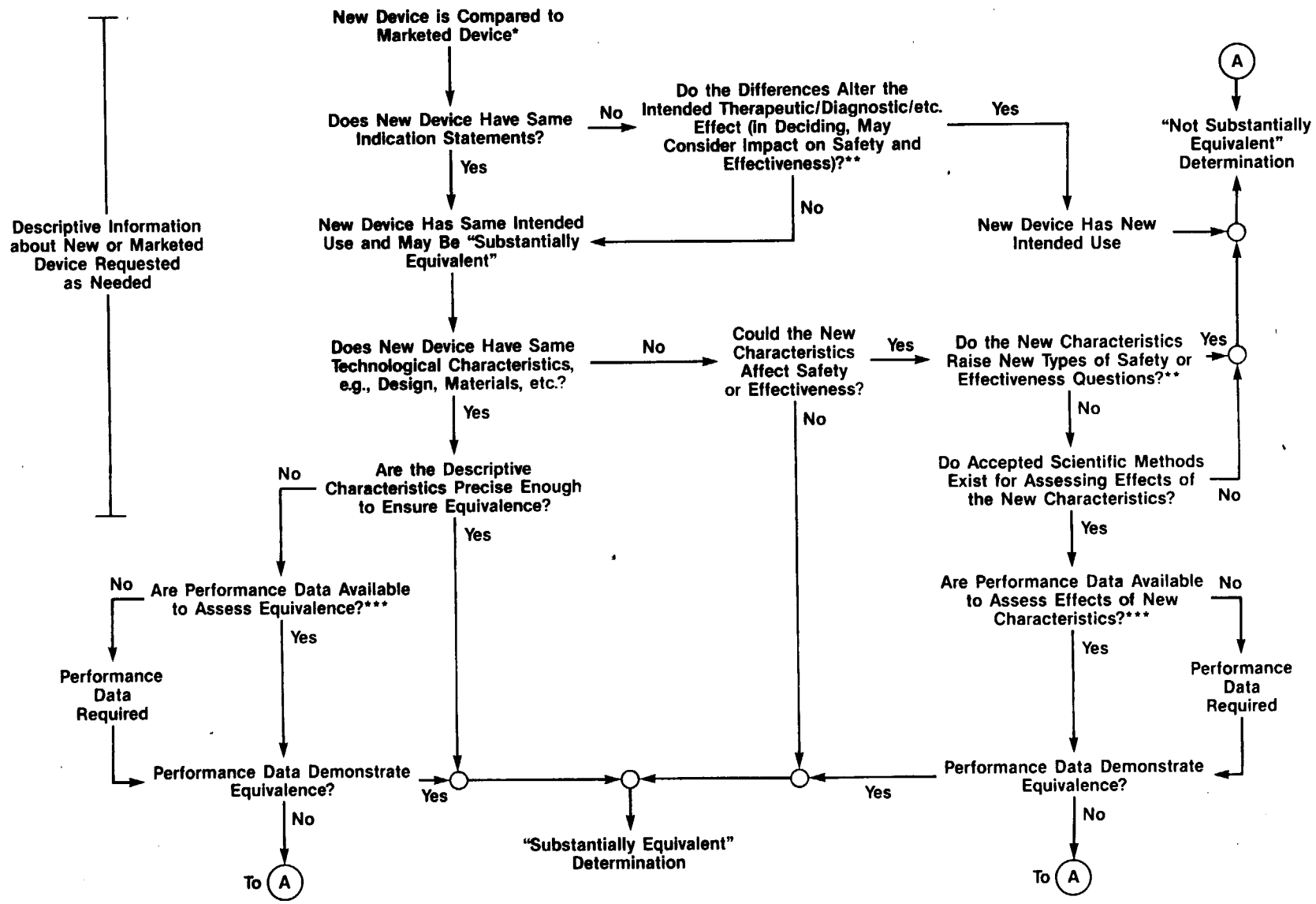
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendments or Reclassified Post-Amendments) Devices is Unclear.

** This Decision is Normally Based on Descriptive Information Alone, But Limited Testing Information is Sometimes Required.

*** Data May Be in the 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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3

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DEPARTMENT OF HEALTH AND HUMAN SERVICES **Public Health Service**

Food and Drug Administration
Center for Devices and
Radiological Health
8757 Georgia Avenue
Silver Spring, MD 20910

FEBRUARY 17, 1989

R & D SYSTEMS, INC.
ATTN: KAREN VISKOCHIL
614 MCKINLEY PLACE N.E.
MINNEAPOLIS, MN 55413

D.C. Number : K890749
Received : 02-13-89
Product : MODIFIED CBC-TECH(TM) HEMATOLOGY CONTROL/MULTIPLE

The Premarket Notification you have submitted as required under Section 510(k) of the Federal Food, Drug and Cosmetic Act for the above referenced device has been received and assigned a unique document control number (D.C. Number above). Please cite this D.C. Number in any future correspondence that relates to this submission.

We will notify you when the processing of this submission has been completed or if any additional information is required. You are required to wait ninety (90) days after the received date shown above or until receipt of a "substantially equivalent" letter before placing the product into commercial distribution. I suggest that you contact us if you have not been notified in writing at the end of this ninety (90) day period before you begin marketing your device. Written questions concerning the status of your submission should be sent to:

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, Maryland 20910

If you have procedural or policy questions, please contact the Division of Small Manufacturers Assistance at their toll-free number (800) 638-2041 or me at (301) 427-8162.

Sincerely yours,

Robert I. Chissler
Premarket Notification Coordinator
Office of Device Evaluation
Center for Devices and
Radiological Health

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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K890749

R&D

FDA-CDRH-ODE

FEB 13 1989

DOCUMENT MAIL CENTER

February 10, 1989

Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
8757 Georgia Avenue
Silver Spring, MD 20910

Dear Sir/Madam:

PREMARKET NOTIFICATION--CBC-TECH™ HEMATOLOGY CONTROL
MODIFICATION OF 510(K) SUBMISSION K874386

In conformance with Section 510(k) of the Food, Drug, and Cosmetic Act as amended by the Medical Device Amendments of 1976, notice is hereby provided of our intent to make a manufacturing change to CBC-Tech Hematology Control. Notification information as follows:

a) Classification Names: Hematology Quality Control Mixture

b) Common/Usual Name: Multiparameter Hematology Control

c) Proprietary Name: CBC-Tech™ Hematology Control/Multiple

d) Owner/Operator: R & D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, Minnesota 55413
Establishment Registration Number: 2182501

e) Classification: Products of this type have been classified by the Clinical Chemistry and Hematology Devices Panel, Hematology/Pathology Section, in Class II (performance standards).

Classification Code: 81JPK Hematology Control Mixtures for Quality Control

f) No performance standards applicable to the above have been established.

g) Package (box)/vial labeling, package insert, and stability data are appended.

h) Description of Change: The formulation of the red blood cell base used in the manufacture of the control product is changed from R & D proprietary formula KH to formula KE7. Formula KE7 is currently used in other hematology controls manufactured by R & D Systems.

R & D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, MN 55413
(612) 379-2956
WATS: (800) 328-2400
Telex: 759627

Questions to FDA/CDRH/OSEL/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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i) Substantial Equivalence. CBC-Tech Hematology Control is substantially equivalent to hematology control mixtures currently on the market.

Hematology Quality Control Mixtures are used to control the WBC, RBC, and PLT counts and related parameters including the white cell differential.

Hematology control mixtures manufactured prior to the Medical Device Amendments of 1976 include:

Coulter 4C^{R} Cell Control (Coulter Electronics, Hialeah, FL), 1968 Labelling was included in 510(k) K874386.

Post enactment hematology control mixtures include:

Technicon^{R} TESTpoint^{TM} Hematology Control (Technicon Instruments Corp., Tarrytown, NY). Labelling was included in 510(k) K874386.

Streck Para TECH^{TM} (Streck Laboratories, Inc., Omaha NE) Labelling was included in 510(k) K874386.

i) This submission is not considered confidential.

Should further information be required, please contact the undersigned at (800) 328-2400.

Submitted by:

Karen Viskochil

Karen Viskochil
Official Correspondent
R & D Systems, Inc.

jh:FDA

Attachments: 1. Labelling for CBC-Tech Hematology Control
Package Insert
Assay Table
Vial Label
Box Label

2. Data Set

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

6

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Labeling for

CBC-Tech Hematology Control

- Package Insert: Instruction Sheet
- Assay Tables
- Vial and Box Labels

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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R&D
R & D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, MN 55413

CBC-Tech™

HEMATOLOGY CONTROLS

INTENDED USE

CBC-Tech™ is a Tri-Level Hematology Control specifically designed to document and monitor values obtained from the Technicon® H•1™ instrument. CBC-Tech is available in three levels representing low, normal, and high levels of the constituents measured. Values are provided for the following parameters:

WBC	leukocyte count
RBC	erythrocyte count
HGB	hemoglobin concentration
HCT	hematocrit
MCV	mean cell volume
MCH	mean cell hemoglobin
MCHC	mean cell hemoglobin concentration
RDW	red cell distribution width
PLT	platelet count
MPV	mean platelet volume
HDW	hemoglobin distribution width
LI	lobularity index
MPXI	mean peroxidase index
NEUT%	neutrophil percent
LYMP%	lymphocyte percent
MONO%	monocyte percent
EOS%	eosinophil percent
BASO%	basophil percent
LUC%	large unstained cell percent
NEUT#	absolute neutrophil count
LYMP#	absolute lymphocyte count
MONO#	absolute monocyte count
EOS#	absolute eosinophil count
BASO#	absolute basophil count
LUC#	absolute large unstained cell count
MNx	X mode of MN population
MNy	Y mode of NM population
BLAST%	blast percent
Kx%	X position of neutrophils relative to normal cytogram
Ky%	Y position of neutrophils relative to normal cytogram
WBCB	leukocyte count obtained from basophil/lobularity channel

SUMMARY AND PRINCIPLE

It is an established laboratory procedure to use stable reference controls to monitor hematology counting systems. CBC-Tech provides a means of determining accuracy, precision and linearity of the hematology testing system. Assay values for CBC-Tech are based on replicate analyses on instruments which have been whole blood calibrated to values obtained from reference methods.

REAGENTS

CBC-Tech contains human erythrocytes, mammalian leukocytes and mammalian platelets in a plasma-like fluid. CBC-Tech is for *in vitro* diagnostic use.

PRECAUTIONS

CBC-Tech is intended solely for *in vitro* diagnostic use by trained, qualified personnel. Human blood components used in CBC-Tech were found to be non-reactive for HBsAg and antibody to HIV when tested with licensed reagents. No known test methods can provide complete assurance that products derived from human blood will not transmit infectious diseases. Follow the same precautions as with patient samples when handling or disposing of CBC-Tech. Do not inject or consume by mouth. Avoid direct mouth pipetting of samples.

STORAGE AND STABILITY

Open vial stability is 14 days, provided the vials are handled properly. CBC-Tech must be mixed according to instructions before each sampling. After sampling, the vial rim and cap should be wiped and the cap immediately replaced. CBC-Tech should be stored, tightly capped, at 2-8°C when not in use. See Instructions for Use section for detailed handling directions. Unopened vials stored continuously at 2-8°C are stable until the expiration date.

INDICATIONS OF DETERIORATION:

Discoloration of the supernatant fluid may be caused by overheating or freezing during shipping or storing. Examine vials for excessive hemolysis. Test the vials using reference methods if deterioration is suspected. Inability to obtain expected values with automated instruments may be due to instrument malfunction, differences in calibration or reagent system, or product deterioration.

INSTRUCTIONS FOR USE:

1. Store at 2-8°C, protect from heat and freezing.
2. Let a vial of CBC-Tech equilibrate to room temperature undisturbed.
3. Roll the vial between the palms of the hands until the erythrocyte sediment is completely resuspended.
4. Immediately prior to use, mix by gently inverting vial 8-10 times.
5. Sample the vial using the same technique as with a normal patient sample.
6. After sampling, carefully wipe the vial rim and cap with lint-free gauze. Replace the cap immediately. Replace vial in refrigerator within 30 minutes of use. Store in an upright position.
7. Read and record results using the same procedures as with a normal patient sample.

RESULTS

Refer to the assay sheet for the assay values for each lot of CBC-Tech. Verify that the lot number on the assay sheet corresponds with the lot number on the control vial in use.

LIMITATIONS

It is not possible to perform a manual leukocyte differential on CBC-Tech.

PERFORMANCE CHARACTERISTICS

The assay values provided are based on replicate analyses on instruments whole blood calibrated to values obtained from reference methods, and using the instrument manufacturers' recommended reagents. Values are presented as a Mean and Expected Range. Each laboratory should establish its own mean values for each lot. The laboratory mean should fall within the Expected Range of Mean Values listed. Laboratories may consider results acceptable when at least 95% of test results are within the laboratory's expected range (the laboratory mean ± the expected range given). An individual laboratory range may include results above or below the Expected Range given.

TECHNICAL ASSISTANCE - CUSTOMER SERVICE

Customers desiring technical assistance are encouraged to call our Technical Service Department at (800) 328-2400, in Minnesota, (612) 379-2956. For additional information on R & D Systems Inc. whole blood and platelet-rich-plasma controls and calibrators call the numbers given and ask for Customer Service.

QUALITY CONTROL PROGRAM

Those laboratories submitting data to R & D Systems Hematology Quality Control Program should note the QCP data month on the assay sheet. Data should be submitted monthly. This month should be recorded on the data submission form.

TRADEMARKS

CBC-Tech™ is a trademark of R & D Systems, Inc., Minneapolis, MN 55413.

TECHNICON® is registered trademark and TECHNICON H•1™ is a trademark of Technicon Instruments Corporation, Tarrytown, NY.

R & D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, MN 55413
USA

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118
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R & D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, MN 55413

CBC-Tech™

CONTROLES HEMATOLOGIQUES

OBJET

Le CBC-Tech™ est un produit de contrôle hématologique à trois niveaux, dont le but est de permettre la maîtrise et le contrôle des valeurs données par l'instrument Technicon® H•1™. Le CBC-Tech est disponible à trois concentrations (basse, moyenne et haute) des éléments mesurés. Les valeurs sont fournies pour les paramètres suivants:

WBC	Nombre de Leucocytes
RBC	Nombre de Globules Rouges
HGB	Concentration en Hémoglobine
HCT	Hématocrite
MCV	Volume Globulaire Moyen
MCH	Teneur Corpusculaire Moyenne en Hémoglobine
MCHC	Concentration Corpusculaire Moyenne en Hémoglobine
RDW	Indice de Distribution des Hématies
PLT	Plaquettes
MPV	Volume Plaquettaire Moyen
HDW	Indice de Distribution de l'Hémoglobine
LI	Index de "Lobularité" des Noyaux
MPXI	Activité Péroxydasique Moyenne
NEUT%	% de Neutrophiles
LYMP%	% de Lymphocytes
MONO%	% de Monocytes
EOS %	% d'Eosinophiles
BASO %	% de Basophiles
LUC%	% de Grandes cellules sans Activité Péroxydasique
NEUT#	Nombre de Neutrophiles
LYMP#	Nombre de Lymphocytes
MONO#	Nombre de Monocytes
EOS#	Nombre d'Eosinophiles
BASO#	Nombre de Basophiles
LUC#	Nombre de Grandes Cellules sans Activité Péroxydasique
MNx	Abscisse du Centre de la Population des Cellules Mononucléées
MNy	Ordonnée du centre de la Population des Cellules Mononucléées
BLAST%	% de Blastes
Kx%	Abscisse du Centre de la Population des Neutrophiles relative à un Cytogramme Normal
Ky%	Ordonnée du Centre de la Population des Neutrophiles relative à un Cytogramme Normal
WBCB	Nombre de leucocytes obtenu à partir du canal basophile/lobularité

PRINCIPE

Il est de pratique courante dans les laboratoires d'analyses médicales d'utiliser des produits de référence stables dans la mise en oeuvre de systèmes de comptages hématologiques. Le CBC-Tech donne un moyen de vérifier l'exactitude, la précision et la linéarité du système hématologique. Les valeurs de référence données pour le CBC-Tech sont basées sur des analyses multiples opérées sur des instruments qui ont été calibrés avec du sang total en tenant compte des valeurs obtenues par des méthodes de référence.

REACTIFS

Le CBC-Tech contient des globules rouges humains, des leucocytes et des plaquettes de mammifères, dans un liquide présentant les caractéristiques du plasma. Le CBC-Tech doit être réservé aux méthodes de diagnostic *in vitro*.

PRECAUTIONS

Le CBC-Tech est destiné exclusivement à l'utilisation pour les diagnostics *in vitro* par du personnel qualifié et entraîné. Le dérivés de sang humain utilisés pour la fabrication du CBC-Tech ont été testés au moyen de réactifs approuvés et trouvés négatifs aux tests HBsAg et HIV. Cependant, aucune méthode de diagnostic ne peut donner l'assurance absolue que des produits dérivés du sang humain ne puissent transmettre de maladie contagieuse. Lors de l'utilisation ou du rejet du flacon, il est recommandé d'utiliser les mêmes précautions que celles prises pour des échantillons en provenance de malades. Le produit ne doit être ni injecté, ni avalé. Eviter le pipettage direct par la bouche.

CONSERVATION ET STABILITE

Les flacons non ouverts, conservés à des températures de 2 à 8°C, sont stables jusqu'à la date d'expiration. Le CBC-Tech doit être agité selon la méthode décrite dans la section mode d'emploi. Les flacons ouverts sont stables pendant 14 jours, s'ils sont utilisés convenablement. Ils doivent être refermés immédiatement après l'usage en ayant soin d'essuyer correctement les bords du col et le bouchon. Conserver les flacons en cours d'utilisation à une température entre 2 et 8°C.

PRODUIT DEFECTUEUX

Un changement dans la couleur du contenu du flacon peut être provoqué par une surchauffe ou un refroidissement excessif pendant le stockage ou l'expédition. Une hémolyse excessive dans les échantillons doit être détectée à l'arrivée.

L'impossibilité d'obtenir les valeurs attendues avec des instruments automatiques peut être due à un mauvais fonctionnement de l'instrument, des différences dans les procédures de calibration ou les systèmes de réactifs ou à la détérioration du produit.

MODE D'EMPLOI

1. Conserver à une température de 2 - 8°C à l'abri de la chaleur et de la congélation.
2. Laisser un flacon de CBC-Tech revenir à température ambiante sans l'agiter.
3. Rouler le flacon entre la paume des mains jusqu'à remise en suspension complète du sédiment globulaire.
4. Immédiatement avant utilisation, mélanger en renversant doucement le flacon 8 à 10 fois.
5. Utiliser le produit comme un sang de patient.
6. Après prélèvement d'un échantillon, essuyer soigneusement la collerette du flacon et le bouchon avec un linge non-pelucheux. Reboucher le flacon immédiatement et le remettre au réfrigérateur dans la demi-heure qui suit l'emploi. Stocker en position verticale.
7. Lire et enregistrer les résultats en utilisant les mêmes procédures que celles mises en oeuvre pour un sang normal de patient

RESULTATS

Se reporter à la fiche de contrôle pour obtenir les valeurs se référant à chaque lot de CBC-Tech. Vérifier que le numéro de lot porté sur la fiche de contrôle correspond avec celui mentionné sur le flacon.

LIMITES D'EMPLOI

Il n'est pas possible de faire des formules sanguines traditionnelles avec le CBC-Tech.

CARACTERISTIQUES

Les valeurs indiquées sont basées sur des analyses multiples effectuées avec des instruments calibrés sur sang total à des valeurs obtenues par des méthodes de référence en utilisant les réactifs recommandés par le fabricant de l'instrument. Les valeurs obtenues indiquent la moyenne et les limites de variations. Chaque laboratoire doit déterminer ses propres valeurs moyennes pour chaque lot. La moyenne pour le laboratoire doit se trouver à l'intérieur de l'intervalle de variations indiqué pour les moyennes. Les laboratoires peuvent considérer les résultats comme acceptables quant au moins 95% des résultats obtenus se trouvent à l'intérieur de l'intervalle de variations du laboratoire (c'est-à-dire la moyenne pour le laboratoire ± la variation donnée). L'intervalle de variations pour un laboratoire donné peut inclure des résultats au-dessus ou au-dessous de l'intervalle de variations indiqué.

MARQUES DEPOSEES

CBC-Tech™ est une marque déposée de R & D Systems, Inc., Minneapolis, MN 55413.

TECHNICON® et TECHNICON H•1™ sont des marques déposées de Technicon Instruments Corporation, Tarrytown, NY.

R & D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, MN 55413
USA

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IS021 (b) Rev. 07

Produit distribué en EUROPE
par:
HYCEL
13, rue du Noyer
35000 RENNES (France)
Tél. 99.53.66.09

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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R & D

R & D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, MN 55413

CBC-TECH
HEMATOLOGY CONTROLS

TECHNICON H-1 VALUES

ASSAY VALUES AND EXPECTED RANGES
VALEURS CIBLES ET INTERVALLE DE VARIATIONS

QCP DATA MONTH: NOVEMBER

EXP. DATE: 5 DECEMBER 86
DATE D'EXP.: 5 DECEMBRE 86

LOW / BAS — LOT# K118L

H-1 CONTROL FILE TEST #	TEST	ASSAY VALUES MOYENNE	RANGES ± LIMITES
1	WBC $10^3/uL$	2.1	0.4
2	RBC $10^6/uL$	1.97	0.09
3	HGB g/dL	5.7	0.3
4	HCT %	14.0	1.5
5	MCV fL	71.0	4.0
6	MCH pg	28.9	1.5
7	MCHC g/dL	40.8	2.5
8	RDW %	13.5	2.0
9	PLT $10^3/uL$	53	12
10	MPV fL	6.5	1.5
13	HDW g/dL	2.0	1.0
	LI	2.4	0.6
11	MPXI	-7.5	8.0
20	NEUT %	46.0	6.0
21	LYMP %	38.8	6.0
22	MONO %	7.6	4.0
23	EOS %	1.1	1.0
24	BASO %	5.0	3.0
25	LUC %	6.5	4.0
14	NEUT $10^3/uL$	0.97	0.30
15	LYMP $10^3/uL$	0.81	0.30
16	MONO $10^3/uL$	0.16	0.10
17	EOS $10^3/uL$	0.02	0.02
18	BASO $10^3/uL$	0.09	0.06
19	LUC $10^3/uL$	0.14	0.10
12	MNx	11.5	2.0
	BLAST* %	5.5	3.0
	Kx %	92	10
	Ky %	98	8
	WBCB $10^3/uL$	3.2	0.4

NORMAL — LOT# K118N

H-1 CONTROL FILE TEST #	TEST	ASSAY VALUES MOYENNE	RANGES ± LIMITES
1	WBC $10^3/uL$	7.1	0.6
2	RBC $10^6/uL$	4.30	0.12
3	HGB g/dL	13.3	0.4
4	HCT %	32.7	2.0
5	MCV fL	76.0	4.0
6	MCH pg	30.9	1.5
7	MCHC g/dL	40.7	2.5
8	RDW %	13.8	2.0
9	PLT $10^3/uL$	210	25
10	MPV fL	6.8	1.5
13	HDW g/dL	2.0	1.0
	LI	2.4	0.6
11	MPXI	-4.4	8.0
20	NEUT %	70.4	6.0
21	LYMP %	19.1	4.0
22	MONO %	5.6	3.0
23	EOS %	1.4	1.0
24	BASO %	4.0	3.0
25	LUC %	3.5	2.0
14	NEUT $10^3/uL$	5.00	0.80
15	LYMP $10^3/uL$	1.36	0.40
16	MONO $10^3/uL$	0.40	0.20
17	EOS $10^3/uL$	0.10	0.08
18	BASO $10^3/uL$	0.28	0.20
19	LUC $10^3/uL$	0.25	0.20
12	MNx	11.5	2.0
	BLAST* %	3.4	2.0
	Kx %	96	10
	Ky %	92	8
	WBCB $10^3/uL$	9.0	0.6

HIGH / HAUT — LOT# K118H

H-1 CONTROL FILE TEST #	TEST	ASSAY VALUES MOYENNE	RANGES ± LIMITES
1	WBC $10^3/uL$	15.9	1.4
2	RBC $10^6/uL$	5.08	0.18
3	HGB g/dL	17.0	0.5
4	HCT %	41.7	2.5
5	MCV fL	82.0	4.0
6	MCH pg	33.5	2.0
7	MCHC g/dL	40.8	2.5
8	RDW %	13.6	2.0
9	PLT $10^3/uL$	415	45
10	MPV fL	7.1	1.5
13	HDW g/dL	1.9	1.0
	LI	2.4	0.6
11	MPXI	-6.4	8.0
20	NEUT %	79.0	4.0
21	LYMP %	13.8	3.0
22	MONO %	4.4	3.0
23	EOS %	0.8	0.8
24	BASO %	3.6	3.0
25	LUC %	2.0	2.0
14	NEUT $10^3/uL$	12.56	1.70
15	LYMP $10^3/uL$	2.19	0.60
16	MONO $10^3/uL$	0.70	0.50
17	EOS $10^3/uL$	0.13	0.13
18	BASO $10^3/uL$	0.57	0.50
19	LUC $10^3/uL$	0.32	0.32
12	MNx	11.5	2.0
	BLAST* %	1.4	1.0
	Kx %	94	10
	Ky %	90	8
	WBCB $10^3/uL$	19.6	1.4

* Blast. Performance characteristics have not been established for this parameter. For research use only.
Blastes. Les caractéristiques des résultats n'ont pas été établies pour ce paramètre. Pour utilisation en recherche uniquement.

ASO21(a) Rev. 2.86

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118

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R & D

R & D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, MN 55413

CBC-TECH
HEMATOLOGY
CONTROLS

ASSAY VALUES AND EXPECTED RANGES
VALEURS CIBLES ET INTERVALLE DE VARIATIONS

EXP. DATE: 5 DECEMBER 86
DATE D'EXP.: 5 DECEMBRE 86

QCP DATA MONTH: NOVEMBER

COULTER S SERIES, ISOTON III REAGENT SYSTEM. WHOLE BLOOD CALIBRATED.

For Coulter Counter® Model S Plus II, III, IV, V, VI, S880, T Series, STKR, JR.

Les instruments sont calibrés avec du sang total.

LOW BAS			NORMAL			HIGH HAUT		
LOT# K118L			LOT# K118N			LOT# K118H		
ASSAY VALUES MOYENNE	RANGES ± LIMITES		ASSAY VALUES MOYENNE	RANGES ± LIMITES		ASSAY VALUES MOYENNE	RANGES ± LIMITES	
3.2	WBC* x 10^3	0.4	9.0	WBC* x 10^3	0.6	19.0	WBC* x 10^3	1.0
1.94	RBC x 10^6	0.09	4.32	RBC x 10^6	0.12	5.13	RBC x 10^6	0.18
5.6	Hgb g/dL	0.3	13.3	Hgb g/dL	0.4	17.4	Hgb g/dL	0.5
15.9	Hct %	1.5	38.0	Hct %	2.0	48.7	Hct %	2.5
82.0	MCV µm3	4	88.0	MCV µm3	4	95.0	MCV µm3	4
28.9	MCH pg	1.0	30.8	MCH pg	1.5	33.9	MCH pg	1.5
35.2	MCHC g/dL	2.0	35.0	MCHC g/dL	2.0	35.7	MCHC g/dL	2.0
13.5	RDW %	2.0	13.9	RDW %	2.0	13.3	RDW %	2.0
50	PLT x 10^3	10	200	PLT x 10^3	20	400	PLT x 10^3	40
7.0	MPV µm3	1.5	7.2	MPV µm3	1.5	7.2	MPV µm3	1.5

* WBC count may backlight.
* Le comptage des globules blancs peut s'imprimer en blanc sur fond noir.

REFERENCE VALUES

VALEURS DE REFERENCE

LOW BAS		NORMAL		HIGH HAUT	
LOT# K118L		LOT# K118N		LOT# K118H	
ASSAY VALUES MOYENNE	RANGES ± LIMITES	ASSAY VALUES MOYENNE	RANGES ± LIMITES	ASSAY VALUES MOYENNE	RANGES ± LIMITES
1.94 RBC x 10^6/uL	0.09	4.25 RBC x 10^6/uL	0.12	5.12 RBC x 10^6/uL	0.18
5.9 Hgb g/dL	0.3	13.3 Hgb g/dL	0.4	17.3 Hgb g/dL	0.5
14.0 SPUN HCT %	1.5	33.0 SPUN HCT %	2.0	43.0 SPUN HCT %	2.5
50 PLT x 10^3/uL	15	215 PLT x 10^3/uL	25	400 PLT x 10^3/uL	50

NOTES:

1. Before using, refer to the instruction sheet for mixing directions.
2. For technical assistance call our Technical Service Department at (800) 328-2400, in Minnesota call (612) 379-2956.
3. Coulter Counter® is a registered trademark of Coulter Electronics, Inc., Hialeah, FL.
4. Technicon H-1 is a trademark of Technicon Corporation, Tarrytown, NY.

REMARQUES:

1. Avant usage: voir le mode d'emploi pour les modalités d'agitation
2. SPUN HCT% = microhématocrite

AS021(b) Rev. 2.86

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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11

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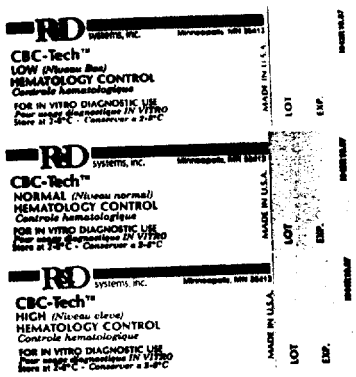
CBC-Tech Vial Labels



CBC-Tech Package (Box) Labels

R&D systems, inc. **CBC-Tech™**
TRI-LEVEL PACK

HEMATOLOGY CONTROL FOR TECHNICON® H•1™ INSTRUMENTS
Four each Low, Normal, High
2.0ml Vials
Cat. No. CT003

KIT EXP.

FOR *IN VITRO* DIAGNOSTIC USE
SEE ACCOMPANYING DIRECTIONS FOR USE.

CONTAINS MAMMALIAN ERYTHROCYTES, LEUKOCYTES
AND PLATELETS
Store at 2-8°C.
R&D systems, inc.
Minneapolis, MN 55413
MADE IN U.S.A.
LB039 REV 10.87

R&D systems, inc. **CBC-Tech™**
DUAL PACK

HEMATOLOGY CONTROL FOR TECHNICON® H•1™ INSTRUMENTS
Five each Low and High
2.0ml Vials
Cat. No. CT002

KIT EXP.

FOR *IN VITRO* DIAGNOSTIC USE
SEE ACCOMPANYING DIRECTIONS FOR USE.

CONTAINS MAMMALIAN ERYTHROCYTES, LEUKOCYTES
AND PLATELETS
Store at 2-8°C.
R&D systems, inc.
Minneapolis, MN 55413
MADE IN U.S.A.
LB038 REV 10.87

R&D systems, inc. **CBC-Tech™**
NORMAL LEVEL

HEMATOLOGY CONTROL FOR TECHNICON® H•1™ INSTRUMENTS
Ten
2.0ml Vials
Cat. No. CT001

KIT EXP.

FOR *IN VITRO* DIAGNOSTIC USE
SEE ACCOMPANYING DIRECTIONS FOR USE.

CONTAINS MAMMALIAN ERYTHROCYTES, LEUKOCYTES
AND PLATELETS
Store at 2-8°C.
R&D systems, inc.
Minneapolis, MN 55413
MADE IN U.S.A.
LB037 REV 10.87

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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CBC-Tech Hematology Control

Data Set

- Closed Vial Stability Data

Lot K108

Low Level 70 Days

Normal Level 71 Days

High Level 69 Days

Lot K118

Low Level 72 Days

Normal Level 72 Days

High Level 72 Days

Lot K128

Low Level 65 Days

Normal Level 65 Days

High Level 65 Days

- Open Vial Stability Data

Low Level Lot K118L 19 Days

Normal Level Lot K118N 19 Days

High Level Lot K118H 16 Days

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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Lot K108L Low Level C[illegible] i Vial Stability Data
Technicon H-1 Instrum[illegible] 70 Days

Line	ID:		WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	NEU	LY	MO	EOS	BAS	LUC	NEU%	LY%	MO%	EOS%	BAS%	LUC%	HDW	LI	MPXI	CHCM	WBCB	XX	XY	MMX	BLA	N=:
09/20	W06	2	2.1	2.04	5.6	14.9	73.1	27.7	37.9	15.8	62	5.7	1.0	0.9	0.2	0.02	0.1	0.1	45.1	42.6	7.6	0.7	5.2	3.9	2.4	2.4	-10.5	38.0	3.0	89	98	11.8	0.6	3
09/21	W06	2	2.1	2.03	5.7	14.9	73.3	27.9	38.0	15.9	57	5.9	1.0	0.9	0.2	0.02	0.1	0.1	44.9	40.1	8.6	0.9	5.6	5.5	2.4	2.2	-12.0	38.0	3.0	88	97	12.0	0.6	3
09/26	W07	2	2.1	1.98	5.7	14.5	73.2	28.5	39.0	15.6	54	6.1	1.0	0.8	0.2	0.01	0.1	0.1	47.6	38.0	8.5	0.5	5.3	5.6	2.2	1.7	-7.0	38.4	2.9	93	101	12.8	0.5	2
10/03	W08	2	2.1	2.09	5.7	15.1	72.1	27.3	37.8	15.2	58	6.2	0.9	0.9	0.2	0.01	0.2	0.1	44.6	40.5	8.7	0.6	7.3	5.7	1.9	2.2	-9.2	38.9	3.0	88	100	10.8	0.8	2
10/10	W09	2	2.2	2.02	5.7	14.4	71.1	28.2	39.6	15.5	53	6.4	1.0	0.8	0.2	0.02	0.2	0.1	46.0	38.8	8.5	0.7	7.3	6.2	1.9	2.2	-3.5	39.0	3.1	96	102	12.0	1.0	2
10/17	W10	2	2.2	2.04	5.7	14.4	70.2	27.7	39.5	15.2	54	5.7	1.0	0.8	0.2	0.02	0.2	0.1	45.0	39.1	9.4	0.9	7.0	5.6	1.8	1.7	-4.4	39.3	3.0	95	96	12.3	1.0	1
10/18	W10	2	2.1	2.00	5.7	14.1	70.3	28.7	40.9	15.1	52	6.7	0.9	0.9	0.2	0.02	0.2	0.1	44.3	40.8	9.6	0.9	7.1	4.4	1.8	1.5	-7.0	39.5	2.9	94	96	12.5	0.9	1
10/19	W10	2	2.1	2.01	5.7	14.0	69.8	28.5	40.8	15.2	52	6.6	0.9	0.9	0.2	0.01	0.2	0.1	44.0	41.6	9.9	0.6	7.0	3.9	1.9	1.3	-6.1	39.5	3.0	94	100	17.5	0.8	1
10/24	W11	2	1.9	2.01	5.7	13.7	68.4	28.5	41.7	15.5	53	6.5	0.9	0.8	0.2	0.02	0.1	0.1	45.3	41.1	9.1	0.8	7.6	3.9	1.9	1.9	-8.8	40.1	2.4	92	97	12.5	1.9	2
10/26	W11	2	2.0	2.11	5.8	15.0	71.1	27.3	38.4	15.3	59	6.5	0.8	0.9	0.2	0.02	0.2	0.1	41.6	43.3	10.4	0.8	8.1	3.9	1.9	1.7	-4.4	39.4	3.0	96	98	12.0	0.9	1
10/31	W12	2	2.0	2.01	5.7	14.2	70.4	28.5	40.5	15.4	52	6.6	0.9	0.8	0.2	0.02	0.1	0.1	44.8	40.5	8.2	1.1	7.6	5.4	2.0	1.7	-6.2	39.5	3.2	94	95	12.3	1.2	2
11/07	W13	2	2.0	2.02	5.7	14.4	71.2	28.3	39.7	15.4	56	6.7	0.9	0.8	0.2	0.01	0.1	0.1	45.3	39.7	10.3	0.6	6.6	4.1	2.0	1.5	-6.6	39.4	3.0	93	100	13.8	1.0	2
11/14	W14	2	2.0	2.00	5.7	14.1	70.4	28.5	40.5	15.5	51	6.9	0.9	0.8	0.2	0.02	0.1	0.1	47.0	39.4	8.1	0.7	6.3	4.8	2.2	1.6	-4.4	39.7	2.9	95	97	11.8	1.2	2
11/15	W14	2	2.1	2.05	5.7	14.3	69.7	27.8	39.9	15.3	50	6.8	1.0	0.8	0.2	0.01	0.1	0.1	46.8	40.2	8.5	0.5	5.9	4.0	2.2	1.6	-7.5	39.4	3.0	93	97	12.5	1.4	2
11/22	W15	2	2.1	1.99	5.7	14.4	72.0	28.4	39.4	15.5	53	7.0	0.9	0.8	0.2	0.02	0.1	0.1	44.6	40.2	9.2	1.1	6.7	5.1	2.3	1.7	-9.7	39.1	3.0	90	97	11.3	1.1	2
11/29	W16	2	2.1	2.03	5.8	14.5	71.3	28.3	39.7	15.7	52	7.3	1.0	0.8	0.2	0.02	0.1	0.1	45.5	39.0	9.7	0.8	5.8	5.2	2.4	1.7	-7.5	39.0	3.1	93	97	12.5	1.3	2

Num/Name:	Mean	Min	Max	Var	StDev	CV	N
1) WBC	2.079	1.9	2.2	0.006	0.078	3.765	31
2) RBC	2.025	1.97	2.11	0.001	0.033	1.647	31
3) HGB	5.687	5.6	5.8	0.002	0.050	0.878	31
4) HCT	14.445	13.7	15.1	0.148	0.386	2.674	31
5) MCV	71.287	68.4	73.5	2.130	1.459	2.047	31
6) MCH	28.081	27.1	28.8	0.220	0.469	1.671	31
7) MCHC	39.410	37.7	41.8	1.378	1.174	2.979	31
8) RDW	15.481	15.0	16.0	0.076	0.276	1.784	31
10) PLT	54.516	49	69	16.125	4.016	7.366	31
11) MPV	6.397	5.0	7.4	0.294	0.543	8.481	31
12) NEU	0.942	0.8	1.0	0.002	0.048	5.116	31
14) LY	0.835	0.8	0.9	0.002	0.046	5.492	31
19) MO	0.184	0.1	0.2	0.001	0.023	12.362	31
20) EOS	0.016	0.01	0.02	0.000	0.005	31.735	31
21) BAS	0.135	0.1	0.2	0.000	0.018	13.276	31
22) LUC	0.101	0.1	0.2	0.001	0.026	25.202	31
23) NEU%	45.310	41.6	49.2	2.308	1.519	3.353	31
24) LY%	40.[illegible]	37.2	43.3	3.[illegible]	1.804	4.446	31
25) MO%	8.[illegible]	6.4	10.4	1.[illegible]	1.079	11.611	31
26) EOS%	0.7[illegible]	0.3	1.1	0.0[illegible]	0.242	28.[illegible]	31
27) BAS%	6.[illegible]	4.8	8.1	0.8[illegible]	0.9[illegible]	14.[illegible]	31
28) LUC%	4.[illegible]	3.2	8.8	1.438	1.199	24.631	31
29) HDW	2.113	1.8	2.4	0.048	0.218	10.334	31
30) LI	1.[illegible]	1.3	2.6	0.127	0.356	19.246	31
31) MPXI	-7.[illegible]	-13.2	-0.9	9.2[illegible]	3.049	-40.363	31
32) CHCM	39.012	37.9	40.2	0.420	0.648	1.661	31
33) WBCB	2.976	2.3	3.2	0.034	0.183	6.163	31
34) XX	92.258	86	98	9.798	3.130	3.393	31
35) XY	98.000	94	102	6.133	2.477	2.527	31
36) MMX	12.323	10.5	17.5	1.592	1.262	10.241	31
37) BLA	0.981	0.4	2.0	0.143	0.378	38.554	31

Num/Name:	Ranges mean+/-	rng	Low	High
1) WBC	2.1	.4	1.7	2.5
2) RBC	2.03	.09	1.94	2.12
3) HGB	5.7	.3	5.4	6.0
4) HCT	14.6	1.5	13.1	16.1
5) MCV	72.0	4	68.0	76.0
6) MCH	28.1	1.5	26.6	29.6
7) MCHC	39.0	2.5	36.5	41.5
8) RDW	15.0	2	13.0	17.0
10) PLT	58	12	46	70
11) MPV	5.8	1.5	4.3	7.3
12) NEU	1.0	.3	0.7	1.3
14) LY	0.9	.3	0.6	1.2
19) MO	0.2	.1	0.1	0.3
20) EOS	0.02	.02	0.00	0.04
21) BAS	0.1	.1	0.0	0.2
22) LUC	0.1	.05	0.0	0.1
23) NEU%	45.2	6	39.2	51.2
24) LY%	40.6	6	34.6	46.6
25) MO%	10.0	4	6.0	14.0
26) EOS%	0.8	.8	0.0	1.6
27) BAS%	6.0	3	3.0	9.0
28) LUC%	3.4	2	1.4	5.4
29) HDW	1.9	1	0.9	2.9
30) LI	2.5	.6	1.9	3.1
31) MPXI	-8.8	8	-16.8	-0.8
	+/-			
32) CHCM	3.0	.4	2.6	3.4
33) WBCB	92	10	82	102
34) XX	98	8	88	104
35) XY	11.0	2	9.0	13.0
36) MMX	1.0	1	0.0	2.0

Questions? Contact [illegible] Recall 301-[illegible] [illegible]nts.gov

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Lot K108N Normal Level 'osed Vial Stability Data
Technicon H-1 Instrum 71 Days

Line	ID:	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	NEU	LY	MO	EOS	BAS	LUC	NEU%	LY%	MO%	EOS%	BAS%	LUC%	HDW	LI	MPXI	CHCM	WBCB	RX	RY	MRX	BL%	N=:
09/19	W06 2	7.2	4.20	13.1	34.9	83.0	31.2	37.5	14.7	219	6.2	5.2	1.3	0.3	0.08	0.3	0.3	72.1	18.5	4.4	1.1	3.6	4.0	2.2	2.6	-5.3	36.8	8.8	95	94	11.8	0.6	6
09/20	W06 2	7.4	4.16	13.1	34.1	82.1	31.6	38.4	14.7	216	6.1	5.4	1.5	0.3	0.08	0.3	0.2	72.1	19.5	4.1	1.0	3.5	3.3	2.2	2.5	-4.4	37.3	8.7	96	91	11.3	0.6	3
09/21	W06 2	7.3	4.20	13.0	34.5	82.2	31.1	37.8	14.7	212	6.3	5.3	1.3	0.3	0.08	0.3	0.3	72.9	17.6	3.9	1.1	3.4	4.5	2.2	2.2	-4.4	37.2	8.7	96	95	12.5	0.6	3
09/26	W07 2	7.3	4.11	13.1	33.9	82.5	32.0	38.8	14.5	214	6.4	5.2	1.4	0.3	0.08	0.3	0.3	72.0	18.9	4.2	1.1	3.7	4.0	1.9	2.2	-3.1	37.5	8.4	97	97	12.8	0.7	2
10/03	W08 2	7.4	4.30	13.1	34.8	81.1	30.6	37.8	14.2	204	6.5	5.3	1.4	0.3	0.07	0.3	0.3	72.4	19.0	3.9	1.0	4.6	3.9	1.7	2.2	-5.7	38.0	8.9	95	96	11.5	0.8	2
10/10	W09 2	7.5	4.21	13.2	33.7	80.0	31.4	39.3	14.2	201	6.6	5.6	1.4	0.3	0.07	0.3	0.3	73.9	18.0	3.4	0.9	4.5	3.9	1.7	2.2	-3.1	38.3	9.1	97	99	11.0	0.9	2
10/17	W10 2	7.3	4.26	13.1	33.6	79.0	30.9	39.1	14.3	209	6.5	5.3	1.3	0.4	0.10	0.3	0.3	71.9	18.3	4.8	1.3	4.7	3.8	1.8	2.0	-3.1	38.5	8.6	97	93	12.3	1.1	2
10/18	W10 2	7.1	4.18	13.2	33.3	79.8	31.6	39.6	14.2	205	6.6	5.2	1.3	0.3	0.09	0.3	0.2	72.8	18.2	4.4	1.1	4.2	3.3	1.7	1.7	-4.4	38.5	8.8	96	96	14.5	0.9	1
10/19	W10 2	7.5	4.17	13.1	32.8	78.8	31.5	40.0	14.1	198	6.6	5.5	1.4	0.3	0.08	0.3	0.2	72.9	19.2	3.9	1.1	4.3	3.0	1.6	2.2	-4.4	38.6	8.6	96	92	10.5	1.1	1
10/24	W11 2	6.9	4.16	13.2	32.4	78.0	31.9	40.9	14.1	208	6.7	5.0	1.3	0.3	0.08	0.3	0.3	71.8	18.6	4.6	1.2	4.9	3.8	1.8	2.1	-3.1	39.0	8.3	97	93	11.8	1.2	4
10/26	W11 2	6.9	4.19	13.2	33.5	80.0	31.6	39.5	14.1	211	6.8	5.0	1.3	0.4	0.09	0.3	0.2	71.8	18.9	5.2	1.3	4.5	2.8	2.1	1.5	-4.4	38.3	8.8	96	96	14.0	1.2	1
10/31	W12 2	6.9	4.10	13.2	32.5	79.2	32.2	40.7	14.2	199	6.8	5.0	1.3	0.3	0.08	0.3	0.2	72.9	18.6	4.1	1.2	4.4	3.4	2.1	1.9	-4.4	38.3	9.0	96	91	62.0	1.2	2
11/07	W13 2	6.8	4.13	13.1	33.1	80.1	31.8	39.6	14.2	200	6.8	4.8	1.3	0.4	0.07	0.3	0.2	70.8	19.8	5.3	1.0	4.1	3.3	2.7	1.9	-2.6	37.6	9.0	98	94	11.8	1.2	2
11/14	W14 2	7.1	4.09	13.1	32.7	80.0	32.1	40.1	14.1	203	6.9	5.1	1.3	0.4	0.09	0.2	0.2	71.6	18.3	5.6	1.3	3.3	3.4	2.9	1.6	-1.4	37.9	8.7	99	93	11.3	1.6	2
11/15	W14 2	7.1	4.23	13.2	33.1	78.3	31.2	39.9	13.9	197	7.0	5.0	1.4	0.4	0.11	0.3	0.2	71.0	19.3	5.6	1.5	3.7	2.7	3.8	1.5	0.0	37.6	8.8	100	94	12.0	1.5	2
11/22	W15 2	7.1	4.10	13.2	33.0	80.6	32.1	39.8	14.0	202	7.1	5.0	1.3	0.4	0.09	0.3	0.2	71.0	18.6	5.8	1.3	3.7	3.4	3.4	1.7	1.8	36.3	8.8	102	93	13.0	1.6	2
11/29	W16 2	7.4	4.14	13.2	33.0	79.8	31.9	40.0	14.4	206	7.1	5.4	1.4	0.3	0.10	0.2	0.2	72.3	18.7	4.5	1.4	3.2	3.2	3.2	1.7	-4.4	37.2	9.1	96	91	12.0	1.6	4

Num/Name:	Mean	Min	Max	Var	StDev	CV	N
1) WBC	7.182	6.8	7.7	0.051	0.226	3.147	39
2) RBC	4.173	4.06	4.31	0.004	0.060	1.435	39
3) HGB	13.128	13.0	13.3	0.006	0.076	0.578	39
4) HCT	33.618	30.9	35.2	0.953	0.976	2.904	39
5) MCV	80.572	75.5	83.2	3.375	1.837	2.280	39
6) MCH	31.510	30.5	32.3	0.231	0.481	1.525	39
7) MCHC	39.131	37.2	42.8	1.574	1.254	3.206	39
8) RDW	14.321	13.6	14.8	0.090	0.299	2.090	39
9) PLT	207.795	194	222	63.746	7.984	3.842	39
10) MPV	6.559	6.1	7.1	0.102	0.319	4.868	39
11) NEU	5.178	4.7	5.8	0.043	0.208	4.026	39
12) LY	1.341	1.2	1.5	0.007	0.081	6.080	39
13) MO	0.322	0.2	0.5	0.004	0.063	19.473	39
14) EOS	0.083	0.06	0.14	0.000	0.015	18.581	39
15) BAS	0.284	0.2	0.4	0.002	0.041	14.371	39
16) LUC	0.261	0.2	0.4	0.004	0.063	24.308	39
17) NEU%	72.082	69.8	74.7	1.134	1.065	1.477	39
18) LY%	18.646	16.4	20.3	0.950	0.975	5.227	39
19) MO%	4.505	2.6	6.3	0.850	0.922	20.464	39
20) EOS%	1.141	0.9	2.0	0.053	0.230	20.178	39
21) BAS%	3.958	3.0	5.1	0.344	0.587	14.816	39
22) LUC%	3.232	2.2	5.6	0.713	0.844	23.290	39
23) HDW	3.628	1.6	5.9	0.423	0.650	18.456	39
24) LI	2.205	1.4	2.7	0.148	0.385	18.054	39
25) MPXI	2.064	1.4	2.7	0.148	0.385	18.654	39
26) CHCM	-3.474	-9.6	1.8	7.581	2.753	-79.240	39
27) WBCB	37.687	36.1	40.0	0.713	0.845	2.241	39
28) RX	8.751	6.5	9.2	0.165	0.407	4.648	39
29) RY	96.821	90	102	6.467	2.543	2.627	39
30) MRX	93.744	88	100	8.459	2.908	3.103	39
31) BL%	14.551	10.5	112.0	257.392	16.043	110.254	39
42) N=	0.990	0.5	1.7	0.140	0.375	37.861	39

Num/Name:	Ranges mean+/- rng	Low	High
1) WBC	7.2 .6	6.6	7.8
2) RBC	4.19 .12	4.07	4.31
3) HGB	13.1 .4	12.7	13.5
4) HCT	33.5 2	31.5	35.5
5) MCV	80.0 4	76.0	84.0
6) MCH	31.3 1.5	29.8	32.8
7) MCHC	39.1 2.5	36.6	41.6
8) RDW	14.0 2	12.0	16.0
9) PLT	215 25	190	240
10) MPV	6.2 1.5	4.7	7.7
11) NEU	5.1 .8	4.3	5.9
12) LY	1.4 .4	1.0	1.8
13) MO	0.5 .2	0.3	0.7
14) EOS	0.09 .07	0.02	0.16
15) BAS	0.3 .2	0.1	0.5
16) LUC	0.2 .1	0.1	0.3
17) NEU%	70.7 6	64.7	76.7
18) LY%	19.3 4	15.3	23.3
19) MO%	6.2 3	3.2	9.2
20) EOS%	1.2 1	0.2	2.2
21) BAS%	4.2 3	1.2	7.2
22) LUC%	2.6 2	0.6	4.6
23) HDW	1.8 1	0.8	2.8
24) LI	2.5 .6	1.9	3.1
25) MPXI	-5.2 8	-13.2	2.8
	+/-		
26) CHCM	8.8 .6	8.2	9.4
27) WBCB	[illegible] 18	[illegible]	106
28) RX	[illegible] 8	87	95
29) RY	12.0 2	10.0	14.0
30) MRX	[illegible] 4	0.0	1.6

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Lot K108H High Level [illegible]ed Vial Stability Data
Technicon H-1 Instru[illegible] 69 Days

Line	ID:	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	NEU	LY	MO	EOS	BAS	LUC	NEU%	LY%	MO%	EOS%	BAS%	LUC%	HDW	LI	MPXI	CHCM	WBCB	KK	KY	MBK	BL%	N=:
09/21	W06 2	16.7	4.84	16.4	41.9	86.7	33.9	39.1	14.4	413	6.3	12.9	2.4	0.7	0.18	0.5	0.5	77.3	14.4	4.5	1.1	3.1	2.8	2.3	2.1	-10.2	37.7	19.6	90	95	12.3	0.5	3
09/26	W07 2	16.4	4.74	16.4	41.0	86.5	34.7	40.1	14.0	411	6.5	12.7	2.2	0.7	0.18	0.5	0.7	77.3	13.2	4.5	1.1	3.1	4.0	2.1	2.4	-8.1	38.0	19.5	93	100	12.5	0.5	4
10/03	W08 2	16.5	4.96	16.6	42.4	85.6	33.4	39.0	14.1	420	6.5	12.7	2.3	0.8	0.14	0.7	0.6	76.8	14.2	4.6	0.9	4.2	3.7	1.9	2.1	-7.0	38.5	20.7	94	98	12.0	0.8	2
10/10	W09 2	16.8	4.85	16.5	40.9	84.2	34.0	40.4	13.8	401	6.6	13.2	2.3	0.7	0.13	0.7	0.6	78.3	13.4	4.1	0.8	4.3	3.6	1.8	2.2	-5.7	38.8	20.5	95	99	12.0	0.8	2
10/17	W10 2	16.6	4.89	16.4	40.5	82.9	33.6	40.5	13.5	411	6.5	12.9	2.3	0.7	0.19	0.7	0.4	78.0	14.1	4.1	1.1	4.2	2.7	1.8	1.9	-4.4	39.1	19.9	96	90	12.0	1.0	2
10/18	W10 2	16.4	4.81	16.4	40.4	84.1	34.1	40.5	14.0	412	6.6	12.7	2.2	0.8	0.19	0.7	0.5	77.5	13.6	4.9	1.2	4.0	2.8	1.8	2.0	-4.4	39.3	20.1	96	92	12.0	1.1	1
10/19	W10 2	16.5	4.80	16.5	39.8	82.9	34.3	41.4	13.5	403	6.6	12.7	2.4	0.8	0.22	0.7	0.5	76.6	14.3	4.8	1.3	4.1	2.9	1.8	1.7	-7.0	39.1	19.6	94	96	12.0	1.1	1
10/24	W11 2	15.6	4.87	16.4	41.2	84.5	33.7	40.0	14.0	394	6.7	12.0	2.2	0.7	0.17	0.7	0.5	77.1	14.1	4.5	1.1	4.2	3.3	2.2	1.7	-8.3	38.9	19.7	92	95	12.0	1.3	2
10/26	W11 2	15.6	4.81	16.5	40.8	84.7	34.4	40.6	14.0	418	6.9	12.0	2.3	0.7	0.18	0.6	0.5	76.6	14.8	4.3	1.1	4.1	3.1	2.2	1.8	-9.6	38.6	20.0	90	92	12.0	1.3	1
10/31	W12 2	15.7	4.73	16.4	39.6	83.9	34.7	41.4	14.1	392	6.8	12.0	2.2	0.8	0.21	0.6	0.4	76.7	13.9	5.3	1.4	4.1	2.8	2.2	1.6	-8.3	39.0	20.3	92	94	12.0	1.5	2
11/07	W13 2	15.7	4.79	16.4	40.5	84.7	34.2	40.4	14.1	399	6.8	12.2	2.3	0.6	0.20	0.6	0.5	77.4	14.3	4.0	1.3	3.7	3.1	2.7	1.7	-7.0	38.3	20.1	94	94	12.0	1.4	2
11/14	W14 2	16.3	4.70	16.4	39.9	84.8	34.8	41.1	14.1	394	6.9	12.5	2.3	0.8	0.19	0.5	0.5	76.5	14.3	5.1	1.2	3.3	3.1	3.6	1.6	-4.0	38.2	20.1	96	92	14.5	1.8	2
11/15	W14 2	16.2	4.86	16.5	40.3	82.9	33.8	40.8	13.6	397	7.0	12.5	2.3	0.7	0.24	0.6	0.5	77.0	14.3	4.5	1.5	3.7	2.8	3.6	1.5	-3.1	38.0	20.7	97	91	12.3	2.1	2
11/22	W15 2	16.1	4.75	16.5	40.6	85.6	34.6	40.5	14.1	403	7.2	12.5	2.2	0.7	0.18	0.6	0.5	77.9	13.5	4.7	1.1	3.6	3.0	2.6	1.3	-5.7	38.4	20.1	95	92	14.5	2.0	2
11/29	W16 2	16.3	4.77	16.4	40.2	84.3	34.4	40.8	14.2	391	7.1	12.5	2.2	0.8	0.30	0.5	0.5	76.5	13.3	5.1	1.8	3.1	3.3	2.8	1.2	-5.7	38.4	20.7	95	93	14.0	1.9	2

Pnum/Pname:	Mean	Min	Max	Var	StDev	CV	N
1) WBC	16.264	15.3	16.9	0.168	0.410	2.521	30
2) RBC	4.806	4.68	4.97	0.006	0.077	1.610	30
3) HGB	16.417	16.3	16.6	0.007	0.083	0.508	30
4) HCT	40.747	39.3	42.5	0.661	0.813	1.995	30
5) MCV	84.800	82.7	87.0	1.677	1.295	1.527	30
6) MCH	34.180	33.3	35.0	0.258	0.507	1.485	30
7) MCHC	40.303	38.9	41.5	0.551	0.743	1.842	30
8) RDW	13.983	13.4	14.5	0.089	0.298	2.134	30
9) PLT	403.867	390	422	107.154	10.352	2.563	30
10) MPV	6.683	6.2	7.2	0.065	0.255	3.811	30
11) NEU	12.557	11.8	13.3	0.144	0.379	3.017	30
12) LY	2.260	2.1	2.4	0.011	0.104	4.607	30
13) MO	0.740	0.5	0.9	0.011	0.107	14.433	30
14) EOS	0.190	0.11	0.36	0.003	0.053	28.090	30
15) BAS	0.601	0.5	0.7	0.006	0.078	12.913	30
16) LUC	0.517	0.4	0.7	0.006	0.076	14.706	30
17) NEU%	77.193	75.8	79.2	0.780	0.883	1.144	30
18) LY%	13.[illegible]	12.8	14.8	0.327	0.572	4.120	30
19) MO%	4.[illegible]	3.0	5.6	0.439	0.663	14.583	30
20) EOS%	1.167	0.7	2.2	0.108	0.328	28.145	30
21) BAS%	3.690	2.9	4.4	0.229	0.478	12.955	30
22) LUC%	3.187	2.7	4.1	0.200	0.447	14.027	30
23) HDW	2.367	1.8	3.7	0.350	0.592	24.994	30
24) LI	1.[illegible]	1.1	2.6	0.152	0.390	21.341	30
25) MPXI	-6.743	-10.5	-1.8	6.007	2.451	-36.345	30
26) CHCM	38.430	37.7	39.3	0.237	0.486	1.266	30
27) WBCB	20.060	19.2	20.8	0.218	0.467	2.327	30
28) KK	93.733	90	98	6.271	2.504	2.672	30
29) KY	94.733	90	102	12.271	3.503	3.698	30
30) MBK	12.583	11.5	17.0	2.088	1.445	11.482	30
31) BL%	1.183	0.4	2.1	0.327	0.572	48.321	30

	Ranges			
Pnum/Pname:	mean+/-	rng	Low	High
1) WBC	16.3	1.4	14.9	17.7
2) RBC	4.86	.18	4.68	5.04
3) HGB	16.5	.5	16.0	17.0
4) HCT	41.3	2.5	38.8	43.8
5) MCV	85.0	4	81.0	89.0
6) MCH	34.0	2	32.0	36.0
7) MCHC	39.9	2.5	37.4	42.4
8) RDW	13.7	2	11.7	15.7
9) PLT	415	45	370	460
10) MPV	6.2	1.5	4.7	7.7
11) NEU	12.5	1.7	10.8	14.2
12) LY	2.3	.7	1.6	3.0
13) MO	1.0	.5	0.5	1.5
14) EOS	0.18	.1	0.08	0.28
15) BAS	0.7	.5	0.2	1.2
16) LUC	0.4	.3	0.1	0.7
17) NEU%	76.6	4	72.6	80.6
18) LY%	14.3	3	11.3	17.3
19) MO%	5.8	3	2.8	8.8
20) EOS%	1.1	1	0.1	2.1
21) BAS%	4.0	3	1.0	7.0
22) LUC%	2.2	2	0.2	4.2
23) HDW	1.8	1	0.8	2.8
24) LI	2.4	.6	1.8	3.0
25) MPXI	-7.8	8	-15.8	0.2
26) CHCM	+/-			
27) WBCB	20.2	1.4	18.8	21.6
28) KK	92	10	82	102
29) KY	92	8	84	100
30) MBK	12.0	2	10.0	14.0
31) BL%	0.6	.6	0.0	1.2

Questions? Contact FDA/CDRH/OC[illegible] 301-796-8[illegible] ©[illegible]s.gov

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Lot K118L Low Level C[illegible] Vial Stability Data
Technicon H-1 Instrum[illegible] 72 Days

Line	ID:	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	NEU	LY	MO	EOS	BAS	LUC	NEU%	LY%	MO%	EOS%	BAS%	LUC%	HDW	LI	MPXI	CHCM	WBCB	KX	KY	MNX	BL%	N=:
10/19	W07 2	2.0	1.95	5.7	14.5	74.3	29.2	39.3	13.7	50	6.5	1.0	0.8	0.1	0.02	0.1	0.2	47.0	37.6	5.8	1.0	4.8	8.6	1.9	2.3	-6.2	38.1	3.2	94	97	10.6	4.6	6
10/24	W08 2	2.0	1.96	5.7	14.7	75.0	29.1	38.8	13.8	54	6.6	0.9	0.8	0.1	0.03	0.1	0.1	45.6	41.3	6.0	1.3	5.3	5.9	1.8	2.5	-7.9	38.4	3.2	93	97	10.5	4.5	2
10/31	W09 2	2.0	1.95	5.7	14.6	75.1	29.2	38.9	13.9	51	6.9	0.9	0.8	0.1	0.02	0.1	0.2	44.5	39.3	7.0	0.7	5.3	8.6	1.7	2.4	-7.9	38.4	3.4	93	96	9.0	4.4	2
11/07	W10 2	2.0	1.94	5.7	14.4	74.3	29.2	39.3	13.5	52	6.6	0.9	0.7	0.1	0.03	0.1	0.2	45.2	37.8	7.4	1.4	4.3	8.3	1.6	2.5	-9.2	38.9	3.2	92	96	10.8	3.8	2
11/14	W11 2	2.0	1.94	5.7	14.3	73.6	29.4	40.0	13.4	51	7.3	0.9	0.8	0.1	0.02	0.1	0.2	44.9	39.6	7.1	0.9	4.4	7.6	1.5	2.6	-8.8	39.4	3.3	90	98	10.5	4.1	2
11/15	W11 2	2.0	1.99	5.7	14.5	72.6	28.7	39.5	13.5	50	7.0	0.9	0.8	0.1	0.02	0.1	0.1	45.4	40.9	6.2	1.1	4.7	6.5	1.5	2.5	-8.3	39.2	3.3	93	96	9.0	3.6	2
11/16	W11 2	2.0	1.94	5.7	14.1	72.8	29.2	40.1	13.6	55	7.1	0.9	0.8	0.2	0.03	0.1	0.2	45.8	38.0	7.6	1.4	5.1	7.3	1.5	2.4	-5.3	39.2	3.4	94	98	9.0	3.5	1
11/21	W12 2	2.0	1.95	5.7	14.5	74.0	29.3	39.6	13.4	47	7.4	1.0	0.7	0.2	0.02	0.1	0.2	47.1	35.9	7.2	0.9	4.1	9.1	1.5	2.4	-7.1	38.9	3.4	93	98	10.8	3.9	2
11/28	W13 2	2.1	1.94	5.7	14.1	72.3	29.3	40.5	13.4	52	6.9	1.0	0.8	0.1	0.02	0.1	0.1	46.9	39.7	6.9	0.8	5.2	6.0	1.5	2.5	-8.4	39.6	3.3	91	97	10.8	3.8	2
12/05	W14 2	2.0	1.96	5.7	14.1	71.7	29.0	40.5	13.5	44	7.7	0.9	0.8	0.1	0.03	0.1	0.1	46.5	39.1	6.9	1.5	4.3	6.0	1.6	2.5	-7.1	39.6	3.3	93	96	9.3	3.2	2
12/08	W14 2	2.0	1.97	5.7	14.1	71.6	28.9	40.4	13.3	46	7.7	0.9	0.8	0.1	0.02	0.1	0.1	44.1	41.6	7.4	1.0	4.9	6.1	1.6	2.7	-7.0	39.3	3.3	94	98	9.5	3.2	2
12/14	W15 2	2.0	1.94	5.7	13.6	70.4	29.5	41.9	13.1	46	7.4	0.9	0.7	0.1	0.03	0.1	0.2	45.8	36.1	6.7	1.3	5.0	10.2	1.7	2.5	-8.8	39.6	3.3	92	96	9.5	2.6	2
12/19	W16 2	2.1	1.93	5.7	13.5	70.4	29.6	42.1	13.7	43	7.7	1.0	0.8	0.2	0.03	0.1	0.1	47.6	38.1	7.8	1.1	5.3	5.5	1.8	2.8	-5.7	39.7	3.3	95	96	10.5	3.6	2
12/29	W17 2	2.0	1.95	5.8	14.0	71.9	29.8	41.5	13.9	50	7.1	1.0	0.8	0.1	0.02	0.1	0.1	49.0	38.3	6.4	1.2	5.4	5.3	2.0	2.7	-4.0	39.8	3.3	96	95	9.0	3.2	2

Fnum/Fname:	Mean	Min	Max	Var	StDev	CV	N
1) WBC	2.020	1.9	2.2	0.003	0.057	2.814	31
2) RBC	1.949	1.91	2.01	0.000	0.020	1.016	31
3) HGB	5.700	5.6	5.8	0.001	0.037	0.641	31
4) HCT	14.235	13.4	14.8	0.130	0.361	2.536	31
5) MCV	73.026	70.3	75.4	2.444	1.563	2.141	31
6) MCH	29.223	28.5	30.1	0.100	0.316	1.081	31
7) MCHC	40.045	38.5	42.4	1.155	1.075	2.684	31
8) RDW	13.558	13.0	14.0	0.079	0.281	2.075	31
9) PLT	48.968	42	58	14.832	3.851	7.865	31
10) MPV	7.042	6.3	7.8	0.201	0.448	6.359	31
11) NEU	0.933	0.8	1.0	0.002	0.046	4.913	31
12) LY	0.782	0.6	0.9	0.005	0.070	8.969	31
13) MO	0.135	0.1	0.2	0.000	0.019	14.279	31
14) EOS	0.023	0.01	0.03	0.000	0.006	25.486	31
15) BAS	0.088	0.1	0.1	0.000	0.010	10.470	31
16) LUC	0.148	0.1	0.3	0.002	0.049	33.065	31
17) NEU%	46.2[illegible]	42.8	49.9	2.225	1.492	3.229	31
18) LY%	38.6[illegible]	31.2	42.7	9.024	3.011	7.787	31
19) MO%	6.687	4.1	8.7	0.870	0.933	13.945	31
20) EOS%	1.074	0.3	1.6	0.043	0.207	26.702	31
21) BAS%	4.816	3.8	5.5	0.261	0.511	10.614	31
22) LUC%	7.385	4.2	13.6	6.268	2.504	33.9[illegible]	31
23) HDW	1.681	1.5	2.0	0.029	0.171	10.174	31
24) LI	2.[illegible]	2.2	2.9	0.027	0.164	6.571	31
25) MPXI	-7.165	-11.4	-2.6	4.534	2.129	-29.722	31
26) CHCM	39.006	38.1	40.0	0.375	0.612	1.569	31
27) WBCB	3.281	3.1	3.4	0.006	0.075	2.288	31
28) KX	93.097	88	98	3.957	1.989	2.137	31
29) KY	96.645	94	100	1.703	1.305	1.350	31
30) MNX	10.016	9.0	12.0	1.725	1.313	13.112	31
31) BL%	3.797	2.3	5.0	0.430	0.655	17.264	31

Fnum/Fname:	Ranges: mean+/-	rng	Low	High
1) WBC	2.1	.4	1.7	2.5
2) RBC	1.97	.09	1.88	2.06
3) HGB	5.7	.3	5.4	6.0
4) HCT	14.0	1.5	12.5	15.5
5) MCV	71.0	4	67.0	75.0
6) MCH	28.9	1.5	27.4	30.4
7) MCHC	40.[illegible]	2.5	38.3	43.3
8) RDW	13.[illegible]	2	11.5	15.5
9) PLT	53	12	41	65
10) MPV	6.5	1.5	5.0	8.0
11) NEU	1.0	.3	0.7	1.3
12) LY	0.8	.3	0.5	1.1
13) MO	0.2	.1	0.1	0.3
14) EOS	0.02	.02	0.00	0.04
15) BAS	0.1	.08	0.0	0.2
16) LUC	0.1	.1	0.0	0.2
17) NEU%	46.0	6	40.0	52.0
18) LY%	38.[illegible]	6	32.8	44.4
19) MO%	7.6	4	3.6	11.6
20) EOS%	1.1	1	0.1	2.1
21) BAS%	5.0	3	2.0	8.0
22) LUC%	6.5	4	2.5	10.5
23) HDW	2.0	1	1.0	3.0
24) LI	2.4	.6	1.8	3.0
25) MPXI	-7.5	8	-15.5	0.5
	+/-			
26) CHCM	3.2	.4	2.8	3.6
27) WBCB	[illegible]	16	[illegible]	102
28) KX	[illegible]	[illegible]	[illegible]	100
29) KY	11.5	5	9.5	13.5
30) MNX	5.5	3	2.5	8.5
31) BL%				

Questions? Contact[illegible]s.gov or call 301-796-8118.

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Lot K118N Normal Level (osed Vial Stability Data
Technicon H-1 Instrum 72 Days

Line ID:	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	NEU	LY	MO	EOS	BAS	LUC	NEU%	LY%	MO%	EOS%	BAS%	LUC%	HDW	LI	MPXI	CHCM	WBCB	KX	KY	MBX	BL%	N=:
10/19 W07 2	6.9	4.31	13.3	34.2	79.3	30.9	39.0	14.2	208	6.6	5.0	1.3	0.3	0.10	0.2	0.3	72.0	18.3	4.1	1.5	3.5	4.2	1.9	2.5	-4.7	37.6	8.8	95	94	11.5	3.0	6
10/24 W08 2	6.7	4.34	13.2	34.7	80.0	30.6	38.2	14.5	216	6.9	4.9	1.3	0.2	0.10	0.2	0.2	72.1	19.6	3.5	1.5	3.5	3.4	1.8	2.4	-5.3	37.9	9.0	95	91	12.0	2.7	2
10/31 W09 2	6.7	4.25	13.3	33.7	79.3	31.2	39.4	14.6	208	7.1	4.8	1.3	0.2	0.10	0.2	0.2	71.7	20.0	3.4	1.4	3.7	3.7	1.6	2.5	-3.1	38.2	9.4	97	92	10.5	2.7	2
11/07 W10 2	6.7	4.34	13.2	34.5	79.4	30.5	38.4	14.2	203	7.0	4.8	1.3	0.2	0.10	0.2	0.3	71.8	19.3	3.6	1.4	3.3	4.0	1.5	2.5	-5.3	38.3	9.2	95	92	9.0	2.6	2
11/14 W11 2	7.0	4.26	13.3	33.6	78.9	31.3	39.6	14.4	205	7.2	5.1	1.3	0.2	0.10	0.3	0.2	72.6	19.2	3.4	1.5	3.6	3.5	1.7	2.6	-4.4	38.6	8.9	96	93	10.0	2.5	2
11/15 W11 2	6.8	4.39	13.2	33.8	76.9	30.0	39.0	13.8	203	7.4	4.9	1.3	0.3	0.10	0.2	0.2	72.6	18.9	3.8	1.5	3.6	3.5	1.9	2.5	0.0	38.7	9.3	100	90	9.0	2.2	2
11/16 W11 2	7.0	4.32	13.3	33.5	77.7	30.7	39.5	14.4	206	7.4	5.0	1.3	0.4	0.13	0.3	0.3	70.8	18.0	5.6	1.8	4.0	3.9	1.5	2.5	-4.4	38.7	9.4	96	90	9.5	2.3	1
11/21 W12 2	7.0	4.23	13.3	33.1	78.3	31.4	40.2	14.1	201	7.5	5.0	1.3	0.3	0.12	0.3	0.3	71.5	18.5	4.2	1.8	3.8	4.2	2.0	2.6	-2.7	38.5	9.1	97	94	9.3	2.2	2
11/28 W13 2	7.1	4.25	13.2	32.7	76.9	31.2	40.6	14.1	210	7.4	5.1	1.4	0.2	0.12	0.2	0.3	72.1	19.2	3.5	1.6	3.4	3.6	1.6	2.5	-5.7	39.0	9.2	95	92	9.3	2.3	2
12/05 W14 2	6.9	4.29	13.2	32.7	76.1	30.9	40.6	14.0	193	7.5	5.0	1.2	0.3	0.11	0.2	0.3	72.7	18.1	3.9	1.6	3.5	3.8	1.7	2.6	-3.5	39.0	9.2	96	92	9.5	2.1	2
12/08 W14 2	6.9	4.32	13.3	32.9	76.1	30.8	40.4	14.1	196	7.4	4.9	1.4	0.3	0.09	0.3	0.3	71.1	19.7	4.3	1.3	3.9	3.7	2.8	2.8	-2.2	38.2	9.3	97	92	9.5	1.8	2
12/14 W15 2	7.0	4.23	13.3	32.1	75.9	31.6	41.7	14.2	201	7.4	5.1	1.3	0.2	0.11	0.3	0.3	72.7	18.3	3.3	1.5	4.0	4.3	2.4	2.7	-4.0	38.6	9.3	96	94	10.0	1.5	2
12/19 W16 2	7.0	4.27	13.3	32.2	75.5	31.2	41.3	14.3	201	7.4	5.0	1.3	0.3	0.14	0.3	0.2	72.2	18.6	4.5	2.0	3.7	2.9	2.0	2.6	0.0	38.9	9.2	100	88	9.5	2.0	2
12/29 W17 2	7.0	4.25	13.4	32.5	76.6	31.6	41.2	14.3	197	7.4	4.9	1.2	0.5	0.13	0.3	0.4	69.5	17.4	6.4	1.8	4.0	5.0	2.8	2.6	1.3	39.0	9.3	102	90	9.3	1.9	2

Num/Name:	Mean	Min	Max	Var	StDev	CV	N
1) WBC	6.902	6.5	7.2	0.024	0.156	2.259	31
2) RBC	4.288	4.18	4.42	0.003	0.055	1.282	31
3) HGB	13.261	13.1	13.4	0.005	0.072	0.539	31
4) HCT	33.374	31.7	34.9	0.754	0.869	2.605	31
5) MCV	77.832	75.4	80.0	2.393	1.547	1.987	31
6) MCH	30.952	29.8	31.9	0.227	0.477	1.540	31
7) MCHC	39.803	38.0	42.1	1.207	1.099	2.760	31
8) RDW	14.190	13.7	14.6	0.064	0.253	1.786	31
9) PLT	203.871	191	217	47.116	6.864	3.367	31
10) MPV	7.152	6.5	7.5	0.107	0.326	4.565	31
11) NEU	4.959	4.6	5.2	0.019	0.138	2.787	31
12) LY	1.293	1.2	1.4	0.004	0.061	4.752	31
13) MO	0.278	0.2	0.5	0.004	0.065	23.499	31
14) EOS	0.107	0.08	0.14	0.000	0.016	14.900	31
15) BAS	0.250	0.2	0.3	0.000	0.021	8.454	31
16) LUC	0.267	0.2	0.4	0.002	0.050	18.652	31
17) NEU%	71.845	69.4	73.8	1.069	1.034	1.439	31
18) LY%	18.739	16.9	20.7	0.896	0.946	5.051	31
19) MO%	4.029	2.7	6.5	0.830	0.911	22.614	31
20) EOS%	1.545	1.2	2.0	0.055	0.234	15.117	31
21) BAS%	3.632	3.2	4.3	0.077	0.277	7.636	31
22) LUC%	3.858	2.9	5.5	0.489	0.699	18.145	31
23) HDW	1.848	1.5	3.4	0.174	0.418	21.432	31
24) LI	2.532	2.4	2.9	0.013	0.112	4.391	31
25) MPXI	-3.287	-9.6	3.5	6.788	2.605	-79.264	31
26) CHCM	38.377	37.5	39.0	0.265	0.515	1.342	31
27) WBCB	9.137	8.7	9.4	0.041	0.204	2.229	31
28) KX	96.774	90	104	6.847	2.617	2.704	31
29) KY	92.065	88	96	5.462	2.337	2.539	31
30) MBX	10.065	9.0	12.0	1.479	1.216	12.084	31
31) BL%	2.339	1.4	3.3	0.222	0.472	20.167	31

Num/Name:	Ranges mean+/-	rng	Low	High
1) WBC	7.1	.6	6.5	7.7
2) RBC	4.30	.12	4.18	4.42
3) HGB	13.3	.4	12.9	13.7
4) HCT	32.7	2	30.7	34.7
5) MCV	76.0	4	72.0	80.0
6) MCH	30.9	1.5	29.4	32.4
7) MCHC	40.7	2.5	38.2	43.2
8) RDW	13.8	2	11.8	15.8
9) PLT	210	25	185	235
10) MPV	6.8	1.5	5.3	8.3
11) NEU	5.0	.8	4.2	5.8
12) LY	1.4	.4	1.0	1.8
13) MO	0.4	.2	0.2	0.6
14) EOS	0.10	.08	0.02	0.18
15) BAS	0.3	.2	0.1	0.5
16) LUC	0.3	.2	0.1	0.5
17) NEU%	70.4	6	64.4	76.4
18) LY%	19.1	4	15.1	23.1
19) MO%	5.6	3	2.6	8.6
20) EOS%	1.4	1	0.4	2.4
21) BAS%	4.0	3	1.0	7.0
22) LUC%	3.5	2	1.5	5.5
23) HDW	2.0	1	1.0	3.0
24) LI	2.4	.6	1.8	3.0
25) MPXI	-4.4	8	-12.4	3.6
26) CHCM	+/-			
27) WBCB	9.0	.6	8.4	9.6
28) KX	96	10	86	106
29) KY	92	8	84	100
30) MBX	11.2	2	9.5	13.5
31) BL%	3.4	2	1.4	5.4

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Lot K118H High Level [illegible]ed Vial Stability Data
Technicon H-1 Instrum[illegible] 72 Days

Line	ID:	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	NEU	LY	MO	EOS	BAS	LUC	NEU%	LY%	MO%	EOS%	BAS%	LUC%	HDW	LI	MPXI	CHCM	WBCB	KX	KY	MNX	BL%	N=:
10/19	W07 2	15.8	5.08	17.0	43.4	85.3	33.5	39.2	13.7	414	6.9	12.7	2.0	0.5	0.12	0.5	0.4	80.5	12.7	3.4	0.8	3.1	2.6	1.8	2.5	-8.3	37.9	18.9	92	90	11.5	1.3	6
10/24	W08 2	15.2	5.09	17.0	43.8	86.0	33.3	38.8	13.9	414	7.1	12.3	2.0	0.4	0.14	0.5	0.4	80.7	13.2	2.9	0.9	3.0	2.3	1.7	2.5	-7.9	38.0	19.4	93	89	11.0	1.2	3
10/31	W09 2	15.3	5.04	17.0	42.8	85.0	33.7	39.7	13.7	407	7.3	12.3	2.0	0.5	0.10	0.5	0.4	80.4	13.0	3.5	0.7	3.2	2.5	1.9	2.5	-6.4	38.0	20.1	94	88	11.0	1.2	3
11/07	W10 2	15.7	4.95	16.7	42.1	84.9	33.7	39.7	14.0	403	7.2	12.3	2.1	0.6	0.18	0.5	0.4	78.6	13.7	3.8	1.2	3.4	2.8	2.8	2.1	-8.5	37.8	20.2	92	93	11.3	1.3	4
11/14	W11 2	15.6	5.01	17.0	42.8	85.4	33.8	39.6	13.9	409	7.5	12.6	2.0	0.6	0.12	0.4	0.4	80.4	12.9	3.5	0.8	2.6	2.5	2.6	2.5	-7.0	37.6	19.7	94	90	12.0	1.2	2
11/15	W11 2	15.6	5.10	17.0	42.6	83.4	33.3	39.9	13.7	410	7.3	12.5	2.0	0.6	0.14	0.5	0.4	79.9	13.1	3.7	0.9	3.0	2.5	2.7	2.6	-5.7	37.7	20.0	95	88	10.5	1.1	2
11/16	W11 2	15.9	5.00	16.9	42.0	84.0	33.9	40.4	13.7	405	7.4	12.5	2.2	0.6	0.13	0.5	0.3	79.1	14.1	3.9	0.8	2.8	2.0	2.8	2.8	-7.0	37.8	19.9	94	88	12.0	1.2	1
11/21	W12 2	15.6	5.00	16.9	42.3	84.7	33.9	40.0	13.6	405	7.5	12.6	2.0	0.5	0.13	0.4	0.4	80.6	12.6	3.5	0.9	2.7	2.7	2.5	2.6	-6.1	37.0	19.8	94	89	9.0	1.2	2
11/28		15.7	5.05	17.0	42.2	83.6	33.7	40.3	13.8	416	7.6	12.6	2.1	0.5	0.12	0.5	0.4	80.4	13.3	3.2	0.8	3.2	2.5	2.7	2.6	-4.9	38.3	20.5	95	88	10.5	1.2	2
12/05	W14 2	15.5	5.09	17.0	42.4	83.2	33.3	39.9	14.0	409	7.6	12.4	2.0	0.5	0.14	0.4	0.4	80.1	13.1	3.5	0.9	2.5	2.4	2.8	2.7	-5.7	38.1	20.0	95	89	9.0	1.1	2
12/08	W14 2	15.4	5.05	17.0	42.0	83.0	33.7	40.6	14.1	405	7.7	12.2	2.1	0.6	0.15	0.5	0.4	79.3	13.4	4.0	1.0	2.9	2.4	3.3	2.6	-4.4	37.2	19.8	96	89	12.0	1.1	2
12/14	W15 2	15.4	4.99	17.0	41.6	83.3	34.1	40.9	14.4	404	7.5	12.3	2.0	0.4	0.26	0.5	0.4	80.2	13.0	2.7	1.7	3.1	2.6	3.6	2.8	-7.0	37.0	20.3	94	91	9.0	1.2	2
12/19	W16 2	15.8	5.02	17.0	41.7	83.1	33.9	40.8	14.5	398	7.5	12.6	2.1	0.7	0.17	0.4	0.3	79.7	13.4	4.4	1.1	2.7	1.6	3.3	2.6	-0.9	37.6	19.6	99	86	10.5	1.1	2
12/29	W17 2	15.8	4.93	17.0	41.5	84.3	34.4	40.9	14.7	397	7.6	12.6	2.0	0.7	0.17	0.4	0.3	79.7	12.8	4.5	1.1	2.8	2.0	3.5	2.6	-1.8	37.4	19.5	98	87	10.5	1.1	2

Item/Name:	Mean	Min	Max	Var	StDev	CV	N
1 [illegible]	15.591	15.1	16.1	0.073	0.271	1.736	35
2 [illegible]	5.032	4.85	5.18	0.006	0.076	1.517	35
3 [illegible]	16.943	16.4	17.1	0.020	0.140	0.826	35
4 [illegible]	42.506	41.1	44.6	0.772	0.879	2.068	35
5 [illegible]	84.457	83.0	86.5	0.995	0.998	1.181	35
6 [illegible]	33.657	32.8	34.5	0.158	0.397	1.180	35
7 [illegible]	39.863	38.1	41.1	0.539	0.734	1.842	35
8 [illegible]	13.931	13.5	14.7	0.113	0.337	2.417	35
9 [illegible]	407.486	393	425	59.434	7.709	1.892	35
10 [illegible]	7.323	6.9	7.7	0.069	0.264	3.599	35
11 [illegible]	12.473	12.1	13.1	0.060	0.245	1.968	35
12 [illegible]	2.042	1.8	2.2	0.008	0.090	4.383	35
13 [illegible]	0.553	0.4	0.8	0.011	0.104	18.751	35
14 [illegible]	0.145	0.09	0.38	0.002	0.050	34.287	35
15 [illegible]	0.465	0.4	0.6	0.002	0.049	10.498	35
16 [illegible]	0.378	0.2	0.6	0.005	0.069	18.123	35
17 [illegible]	80.000	76.9	81.3	0.889	0.943	1.179	35
18 [illegible]	13.089	11.5	14.1	0.273	0.523	3.995	35
19 [illegible]	3.894	2.2	4.8	0.418	0.645	16.556	35
20 [illegible]	0.931	0.6	2.5	0.107	0.327	35.107	35
21 [illegible]	2.937	2.5	3.9	0.097	0.311	10.435	35
22 [illegible]	2.429	1.4	3.9	0.199	0.446	18.376	35
23 [illegible]	2.547	1.6	4.0	0.485	0.697	27.360	35
24 [illegible]	2.516	1.7	2.8	0.047	0.216	8.533	35
25 [illegible]	-6.388	-10.5	-0.9	6.499	2.549	-40.217	35
26 [illegible]	37.720	36.7	38.4	0.189	0.435	1.153	35
27 [illegible]	19.726	18.6	20.8	0.280	0.529	2.682	35
28 [illegible]	94.229	90	100	5.593	2.365	2.510	35
29 [illegible]	89.314	86	98	5.869	2.423	2.712	35
30 [illegible]	10.800	9.0	12.0	2.224	1.491	13.807	35
31 [illegible]	1.186	1.0	1.4	0.015	0.124	10.459	35

Item/Name:	Ranges mean+/-	rng	Low	High
1 [illegible]	15.9	1.4	14.5	17.3
2 [illegible]	5.08	.18	4.90	5.26
3 [illegible]	17.0	.5	16.5	17.5
4 [illegible]	41.7	2.5	39.2	44.2
5 [illegible]	82.0	4	78.0	86.0
6 [illegible]	33.5	2	31.5	35.5
7 [illegible]	40.8	2.5	38.3	43.3
8 [illegible]	13.6	2	11.6	15.6
9 [illegible]	415	45	370	460
10 [illegible]	7.1	1.5	5.6	8.6
11 [illegible]	12.6	1.7	10.9	14.3
12 [illegible]	2.4	.8	1.6	2.8
13 [illegible]	0.7	.5	0.2	1.2
14 [illegible]	0.13	.13	0.00	0.26
15 [illegible]	0.6	.5	0.1	1.1
16 [illegible]	0.3	.32	0.0	0.6
17 [illegible]	79.0	4	75.0	83.0
18 [illegible]	13.8	3	10.8	16.8
19 [illegible]	4.4	3	1.4	7.4
20 [illegible]	0.8	.8	0.0	1.6
21 [illegible]	3.6	3	0.6	6.6
22 [illegible]	2.0	2	0.0	4.0
23 [illegible]	1.9	1	0.9	2.9
24 [illegible]	2.4	.6	1.8	3.0
25 [illegible]	-6.4	8	-14.4	1.6
26 [illegible]	+/-			
27 [illegible]	19.6	1.4	18.2	21.0
28 [illegible]	94	10	84	104
29 [illegible]	90	8	82	98
30 [illegible]	11.3	2	9.3	13.3
31 [illegible]	1.4	1	0.4	2.4

Questions? Contact [illegible]ns.gov call 301-796-[illegible]

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Low K128L Low Level Closed Vial Stability Data
Technicon H-1 Instrument 65 Days

Line ID:	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	NEU	LY	MO	EOS	BAS	LUC	NEU%	LY%	MO%	EOS%	BAS%	LUC%	HDW	LI	MPXI	CHCM	NBCB	KX	KY	MHX	BL%	N=:
11/28 W10 2	2.1	2.00	5.8	14.2	70.7	29.0	40.9	17.5	59	6.4	0.9	0.7	0.3	0.04	0.2	0.2	42.4	34.9	13.8	1.8	10.7	7.3	1.8	2.3	-3.1	39.5	3.0	96	91	11.8	0.5	2
12/05 W11 2	2.0	2.04	5.7	14.3	70.1	28.3	40.3	17.3	52	6.9	0.8	0.7	0.3	0.03	0.2	0.1	40.6	36.3	14.9	1.5	9.8	7.0	1.8	2.2	-1.8	39.4	3.0	98	92	12.5	0.4	2
12/08 W11 2	2.0	2.01	5.8	14.1	70.0	28.8	41.2	17.5	54	7.1	0.8	0.8	0.3	0.04	0.2	0.1	40.8	37.6	14.9	1.8	10.5	5.0	1.9	2.5	-2.7	39.1	3.0	98	94	12.3	0.6	2
12/14 W12 2	2.1	2.00	5.8	13.9	69.6	29.0	41.7	17.4	52	7.0	0.8	0.8	0.3	0.04	0.2	0.2	39.9	36.7	14.4	1.7	11.5	7.3	1.9	1.7	-2.2	39.4	3.0	98	91	13.6	0.6	4
12/19 W13 2	2.0	1.99	5.8	13.8	69.2	29.1	42.0	17.7	50	6.8	0.8	0.7	0.3	0.03	0.2	0.1	41.2	36.4	15.1	1.3	11.9	6.2	2.0	2.1	1.4	39.6	3.0	101	92	12.5	0.6	2
12/27 W14 2	2.1	2.02	5.8	14.2	70.4	28.7	40.8	17.5	52	6.8	0.8	0.7	0.3	0.04	0.2	0.2	39.3	35.3	15.8	2.1	11.7	7.6	2.1	1.6	-1.8	39.4	3.0	99	92	13.5	0.8	2
01/03 W15 2	2.1	1.98	5.8	14.1	71.3	29.4	41.2	17.6	54	7.0	0.8	0.8	0.3	0.04	0.2	0.1	38.8	39.7	15.0	1.7	11.5	4.9	2.2	1.4	0.9	40.2	3.0	101	90	14.0	0.7	2
01/11 W16 2	2.2	2.03	5.8	14.3	70.0	28.7	41.1	17.1	54	6.7	0.9	0.8	0.3	0.04	0.3	0.1	42.7	37.0	14.0	1.6	12.6	4.8	2.4	2.1	2.7	39.5	3.0	102	91	15.3	0.5	2
01/17 W17 2	2.1	1.99	5.8	14.0	70.3	29.3	41.6	17.7	53	7.1	0.9	0.8	0.3	0.03	0.3	0.1	41.1	36.4	16.0	1.7	13.1	5.0	2.5	1.9	-0.9	39.6	3.0	99	91	14.0	0.4	2
01/30 W19 2	2.1	2.02	5.7	14.2	70.1	28.4	40.6	17.7	49	7.1	0.9	0.6	0.3	0.04	0.3	0.3	42.6	27.3	15.4	1.7	13.0	13.1	2.9	1.5	0.9	39.0	3.1	100	92	14.5	0.5	2

Num/Name:	Mean	Min	Max	Var	StDev	CV	N
1) WBC	2.080	2.0	2.2	0.004	0.060	2.867	22
2) RBC	2.005	1.95	2.04	0.001	0.022	1.118	22
3) HGB	5.782	5.7	5.8	0.002	0.039	0.683	22
4) HCT	14.055	13.6	14.4	0.041	0.202	1.435	22
5) MCV	70.082	69.0	71.4	0.346	0.588	0.839	22
6) MCH	28.864	28.1	29.9	0.159	0.398	1.380	22
7) MCHC	41.168	40.0	42.4	0.362	0.602	1.462	22
8) RDW	17.473	16.9	18.0	0.102	0.319	1.829	22
9) PLT	52.636	48	59	8.242	2.871	5.454	22
10) MPV	6.873	6.3	7.2	0.052	0.227	3.305	22
11) NEU	0.850	0.8	1.0	0.002	0.046	5.467	22
12) LY	0.745	0.4	0.9	0.010	0.102	13.710	22
13) MO	0.309	0.3	0.4	0.001	0.028	8.925	22
14) EOS	0.034	0.02	0.05	0.000	0.007	19.540	22
15) BAS	0.240	0.2	0.3	0.001	0.027	11.076	22
16) LUC	0.145	0.1	0.4	0.006	0.077	53.406	22
17) NEU%	40.832	36.9	44.7	4.020	2.005	4.911	22
18) LY%	35.809	17.0	41.4	23.236	4.820	13.461	22
19) MO%	14.868	12.3	17.1	1.480	1.217	8.183	22
20) EOS%	1.629	0.8	2.5	0.099	0.314	18.996	22
21) BAS%	11.591	9.7	13.4	1.138	1.067	9.204	22
22) LUC%	6.832	3.9	19.6	13.030	3.610	52.837	22
23) HDW	2.118	1.8	2.9	0.116	0.340	16.049	22
24) LI	1.907	1.1	2.8	0.229	0.478	25.079	22
25) MPXI	-0.795	-5.3	4.4	6.834	2.614	-328.63	22
26) CHCM	39.445	39.0	40.2	0.092	0.304	0.769	22
27) NBCB	3.016	2.9	3.1	0.004	0.061	2.006	22
28) KX	99.091	94	104	5.991	2.448	2.470	22
29) KY	91.545	88	96	3.403	1.845	2.015	22
30) MHX	13.409	10.5	16.0	2.134	1.461	10.895	22
31) BL%	0.550	0.3	1.0	0.033	0.182	33.077	22

Num/Name:	Ranges mean+/-	rng	Low	High
1) WBC	2.1	.4	1.7	2.5
2) RBC	2.03	.09	1.94	2.12
3) HGB	5.7	.3	5.4	6.0
4) HCT	14.6	1.5	13.1	16.1
5) MCV	72.0	4	68.0	76.0
6) MCH	28.1	1.5	26.6	29.6
7) MCHC	39.0	2.5	36.5	41.5
8) RDW	16.5	2	14.5	18.5
9) PLT	55	12	43	67
10) MPV	6.5	1.5	5.0	8.0
11) NEU	0.8	.3	0.5	1.1
12) LY	0.8	.3	0.5	1.1
13) MO	0.3	.1	0.2	0.4
14) EOS	0.03	.03	0.00	0.06
15) BAS	0.2	.1	0.1	0.3
16) LUC	0.1	.07	0.0	0.2
17) NEU%	39.9	6	33.9	45.9
18) LY%	38.0	6	32.0	44.0
19) MO%	16.0	4	12.0	20.0
20) EOS%	1.6	1	0.6	2.6
21) BAS%	10.5	4	6.2	14.2
22) LUC%	4.5	3	1.5	7.5
23) HDW	1.9	1	0.9	2.9
24) LI	2.1	.6	1.5	2.7
25) MPXI	-3.0	8	-11.0	5.0
26) CHCM	+/-			
27) NBCB	2.9	.4	2.5	3.3
28) KX	98	10	88	108
29) KY	92	8	84	100
30) MHX	11.0	2	9.0	13.0
31) BL%	1.0	1	0.0	2.0

Questions? Contact fda.hhs.gov or call 301-796-8118.

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Lot K128N Normal Level osed Vial Stability Data
Technicon H-1 Instrum 65 Days

Line	ID:		WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	NEU	LY	MO	EOS	BAS	LUC	NEU%	LY%	MO%	EOS%	BAS%	LUC%	HDW	LI	MPXI	CHCM	WBCB	RX	RY	MRX	BL%	N=:
11/28	W10	2	7.5	4.15	13.1	32.5	78.4	31.7	40.4	14.7	211	6.4	4.9	1.6	0.6	0.15	0.5	0.3	65.7	21.0	7.5	2.0	6.4	4.0	1.6	2.5	-8.3	38.8	8.4	93	92	12.8	0.4	2
12/05	W11	2	7.0	4.18	13.1	32.4	77.6	31.3	40.4	14.8	205	6.6	4.8	1.4	0.5	0.14	0.4	0.3	67.9	19.3	7.0	1.9	6.0	4.0	1.6	2.2	-6.6	39.0	8.4	94	89	14.3	0.4	2
12/08	W11	2	7.0	4.20	13.2	32.5	77.5	31.4	40.5	14.8	204	6.6	4.7	1.4	0.5	0.13	0.5	0.3	67.2	19.2	7.2	1.8	6.9	4.7	1.6	2.2	-7.0	38.8	8.4	93	91	13.5	0.6	2
12/14	W12	2	7.1	4.13	13.1	32.0	77.4	31.9	41.1	14.8	207	6.4	4.9	1.3	0.4	0.12	0.5	0.3	68.4	19.0	6.2	1.7	6.8	4.8	1.7	1.9	-7.0	38.8	8.6	94	92	14.0	0.6	2
12/19	W13	2	7.1	4.11	13.1	31.7	77.0	31.9	41.4	14.8	208	6.3	4.8	1.5	0.6	0.15	0.5	0.2	67.1	20.6	8.1	2.1	7.0	2.3	1.7	2.0	-4.4	39.0	8.7	96	88	13.3	0.5	2
12/27	W14	2	7.2	4.16	13.2	32.5	78.2	31.7	40.5	15.0	206	6.6	4.7	1.5	0.6	0.13	0.5	0.2	66.3	20.7	8.5	1.9	7.6	2.7	2.3	2.3	-1.8	38.7	8.5	98	90	14.3	0.4	2
01/03	W15	2	7.0	4.10	13.3	32.6	79.7	32.3	40.6	15.0	200	6.9	4.8	1.4	0.5	0.12	0.5	0.2	68.0	20.3	7.1	1.7	7.4	3.0	2.0	2.0	-1.8	39.3	8.6	98	84	13.5	0.6	2
01/11	W16	2	7.1	4.20	13.4	32.5	77.4	31.9	41.2	15.4	206	6.7	4.8	1.2	0.6	0.15	0.5	0.3	68.2	16.4	8.8	2.1	7.5	4.6	2.2	3.0	-1.8	39.2	8.5	98	87	13.8	0.5	2
01/17	W17	2	7.1	4.16	13.3	32.5	78.0	31.8	40.8	15.1	206	6.6	4.8	1.3	0.6	0.15	0.5	0.3	67.9	17.8	8.1	2.2	7.6	4.2	2.9	2.2	-4.4	38.7	8.6	96	89	15.3	0.5	2
01/30	W19	2	7.4	4.23	13.2	33.0	77.8	31.2	40.1	15.7	203	7.2	5.0	1.3	0.6	0.15	0.6	0.4	67.7	17.1	7.8	2.0	8.0	5.5	2.6	2.0	-7.0	38.6	8.4	94	91	13.3	0.6	2

Pnum/Pname:		Mean	Min	Max	Var	StDev	CV	N
1)	WBC	7.153	6.9	7.5	0.034	0.186	2.594	20
2)	RBC	4.160	4.07	4.26	0.003	0.053	1.267	20
3)	HGB	13.180	13.1	13.4	0.010	0.101	0.763	20
4)	HCT	32.385	31.4	33.2	0.208	0.456	1.407	20
5)	MCV	77.845	76.8	79.8	0.563	0.751	0.964	20
6)	MCH	31.645	31.0	32.5	0.145	0.380	1.200	20
7)	MCHC	40.675	39.8	41.7	0.268	0.518	1.273	20
8)	RDW	14.995	14.7	15.7	0.107	0.327	2.180	20
9)	PLT	205.250	199	216	19.776	4.447	2.167	20
11)	MPV	6.610	6.2	7.2	0.062	0.249	3.767	20
12)	NEU	4.819	4.6	5.2	0.014	0.120	2.498	20
13)	LY	1.368	1.1	1.7	0.028	0.167	12.229	20
14)	MO	0.544	0.3	0.7	0.005	0.069	12.639	20
15)	EOS	0.137	0.10	0.17	0.000	0.020	14.896	20
16)	BAS	0.506	0.4	0.6	0.002	0.049	9.659	20
17)	LUC	0.282	0.2	0.5	0.008	0.092	32.574	20
18)	NEU%	67.415	65.5	69.7	1.482	1.218	1.806	20
19)	LY%	19.120	15.4	22.3	4.585	2.141	11.199	20
20)	MO%	7.610	4.8	9.5	0.921	0.960	12.611	20
21)	EOS%	1.915	1.5	2.4	0.073	0.270	14.101	20
22)	BAS%	7.085	5.9	8.2	0.392	0.626	8.835	20
23)	LUC%	3.955	2.2	6.4	1.637	1.280	32.354	20
24)	HDW	2.021	1.6	2.9	0.197	0.443	21.946	20
25)	LI	2.230	1.4	3.3	0.212	0.461	20.658	20
26)	MPXI	-5.005	-9.6	-1.8	7.594	2.756	-55.060	20
27)	CHCM	38.861	38.5	39.3	0.050	0.224	0.576	20
28)	WBCB	8.505	8.3	8.8	0.016	0.126	1.478	20
29)	RX	95.400	90	98	5.516	2.349	2.462	20
30)	RY	89.300	84	92	6.432	2.536	2.840	20
31)	MRX	13.775	12.0	17.0	1.723	1.313	9.529	20
32)	BL%	0.480	0.3	0.7	0.009	0.095	19.822	20

Pnum/Pname:		Ranges mean+/-	rng	Low	High
1)	WBC	7.1	.6	6.5	7.7
2)	RBC	4.21	.12	4.09	4.33
3)	HGB	13.1	.4	12.7	13.5
4)	HCT	33.3	2	31.3	35.3
5)	MCV	79.0	4	75.0	83.0
6)	MCH	31.1	1.5	29.6	32.6
7)	MCHC	39.4	2.5	36.9	41.9
8)	RDW	14.8	2	12.8	16.8
9)	PLT	205	25	180	230
11)	MPV	6.5	1.5	5.0	8.0
12)	NEU	4.7	.8	3.9	5.5
13)	LY	1.4	.4	1.0	1.8
14)	MO	0.6	.3	0.3	0.9
15)	EOS	0.13	.1	0.03	0.23
16)	BAS	0.4	.3	0.1	0.7
17)	LUC	0.3	.1	0.2	0.4
18)	NEU%	66.8	6	60.8	72.8
19)	LY%	19.4	4	15.4	23.4
20)	MO%	8.4	4	4.4	12.4
21)	EOS%	1.9	1	0.9	2.9
22)	BAS%	6.2	4	2.2	10.2
23)	LUC%	3.5	2	1.5	5.5
24)	HDW	2.5	1	0.8	3.8
25)	LI	2.2	.6	1.6	2.8
26)	MPXI	-7.0	8	-15.0	1.0
27)	CHCM	+/-			
28)	WBCB	8.4	6	2.4	14.4
29)	RX	94	10	84	104
30)	RY	90	8	82	98
31)	MRX	11.5	2	9.5	13.5
32)	BL%	0.5	.5	0.0	1.0

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Lot K128H High Level ed Vial Stability Data
Technicon H-1 Instrum 65 Days

Line	ID:		WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	NEU	LY	MO	EOS	BAS	LUC	NEU%	LY%	MO%	EOS%	BAS%	LUC%	HDW	LI	MPXI	CHCM	WBCB	KX	KY	MEX	BL%	N=:
11/28	W07	2	16.2	5.07	17.0	43.3	85.4	33.6	39.3	13.8	417	7.0	13.2	1.8	0.6	0.12	0.5	0.4	81.4	11.4	3.9	0.8	3.4	2.6	2.2	2.5	-9.7	38.1	20.4	91	92	11.5	0.7	4
11/28			16.6	5.09	17.0	44.4	87.2	33.5	38.4	13.7	418	6.5	13.7	1.6	0.8	0.13	0.6	0.5	82.4	9.5	4.6	0.8	3.6	2.8	1.8	2.5	-14.5	37.9	20.3	86	95	12.5	0.3	2
12/05	W08	2	16.3	5.12	17.1	43.7	85.3	33.5	39.2	13.3	406	6.6	13.4	1.5	0.8	0.15	0.5	0.5	82.3	9.1	4.9	0.9	3.2	2.8	1.6	2.5	-13.2	38.3	20.0	86	97	13.3	0.3	2
12/08	W08	2	15.8	5.05	17.1	42.7	84.6	33.9	40.1	13.4	400	6.5	13.0	1.5	0.7	0.13	0.6	0.5	82.5	9.3	4.6	0.8	3.7	3.0	1.6	2.7	-11.9	38.3	20.0	88	98	12.3	0.3	2
12/14	W09	2	16.3	4.97	17.1	41.8	84.2	34.3	40.7	13.2	405	6.4	13.4	1.5	0.8	0.11	0.6	0.6	82.3	8.9	4.8	0.7	3.6	3.4	2.2	2.5	-11.4	38.1	19.8	89	99	13.0	0.3	2
12/19	W10	2	16.0	4.97	16.9	41.5	83.5	34.1	40.8	13.2	396	6.4	13.1	1.4	0.9	0.15	0.6	0.5	81.5	8.9	5.8	0.9	3.6	3.0	2.2	1.9	-7.5	38.7	20.4	93	96	13.0	0.3	2
12/27	W11	2	16.3	5.04	17.1	42.6	84.4	33.8	40.1	13.5	401	6.6	13.4	1.5	0.9	0.16	0.6	0.4	82.1	9.1	5.5	1.0	3.6	2.4	2.7	2.4	-10.1	38.8	19.9	91	96	14.0	0.3	2
01/03	W12	2	15.9	4.98	17.2	43.0	86.3	34.5	40.0	13.9	398	6.8	13.0	1.5	0.9	0.19	0.6	0.4	81.7	9.5	5.4	1.2	3.9	2.4	2.0	2.0	-10.1	39.3	20.5	90	95	13.3	0.3	2
01/11	W13	2	16.6	5.09	17.3	42.2	82.9	33.9	40.9	13.4	404	6.5	13.6	1.5	0.9	0.19	0.6	0.4	82.0	9.1	5.4	1.1	3.6	2.5	2.8	2.5	-8.8	38.7	19.9	92	99	13.3	0.4	2
01/17	W14	2	16.4	5.00	17.2	41.9	83.9	34.4	41.0	13.3	392	6.6	13.3	1.5	0.9	0.22	0.6	0.4	81.5	9.3	5.2	1.4	3.7	2.7	2.7	2.0	-11.4	38.0	20.3	88	97	13.8	0.3	2
01/30	W16	2	16.7	5.11	17.2	42.4	83.1	33.7	40.6	13.8	404	6.9	13.7	1.4	0.9	0.14	0.6	0.6	81.9	8.7	5.4	0.8	3.9	3.4	2.9	2.4	-8.3	38.8	20.1	93	98	13.5	0.4	2

Pnum/Pname:	Mean	Min	Max	Var	StDev	CV	N
1) WBC	16.270	15.5	17.0	0.149	0.386	2.374	24
2) RBC	5.044	4.92	5.15	0.004	0.063	1.241	24
3) HGB	17.075	16.9	17.3	0.012	0.111	0.652	24
4) HCT	42.704	41.1	45.0	1.009	1.005	2.352	24
5) MCV	84.667	82.9	87.7	2.234	1.495	1.765	24
6) MCH	33.871	33.2	34.6	0.151	0.388	1.147	24
7) MCHC	40.013	37.8	41.1	0.875	0.935	2.338	24
8) RDW	13.504	13.2	14.0	0.085	0.291	2.156	24
9) PLT	404.625	386	422	101.549	10.077	2.490	24
10) MPV	6.633	6.4	7.6	0.099	0.314	4.740	24
11) NEU	13.323	12.5	13.9	0.132	0.363	2.726	24
12) LY	1.542	1.3	2.1	0.036	0.189	12.229	24
13) MO	0.802	0.4	1.0	0.014	0.119	14.827	24
14) EOS	0.149	0.10	0.23	0.001	0.035	23.732	24
15) BAS	0.583	0.5	0.7	0.002	0.045	7.777	24
16) LUC	0.453	0.3	0.6	0.006	0.076	16.820	24
17) NEU%	81.900	79.9	82.6	0.386	0.621	0.759	24
18) LY%	9.496	7.9	13.6	1.567	1.252	13.181	24
19) MO%	4.921	2.8	6.2	0.495	0.703	14.294	24
20) EOS%	0.913	0.6	1.4	0.049	0.221	24.250	24
21) BAS%	3.571	3.0	4.0	0.062	0.249	6.982	24
22) LUC%	2.779	2.1	3.8	0.201	0.448	16.126	24
23) HDW	2.229	1.6	3.4	0.294	0.542	24.094	24
24) LI	2.373	1.3	2.8	0.161	0.401	16.913	24
25) MPXI	-10.529	-15.8	-4.4	10.916	3.304	-31.379	24
26) CHCM	38.408	37.8	39.3	0.189	0.435	1.133	24
27) WBCB	20.180	19.7	20.8	0.096	0.309	1.535	24
28) KX	89.750	86	96	12.630	3.554	3.960	24
29) KY	96.083	88	100	9.558	3.092	3.218	24
30) MEX	12.896	9.0	14.0	1.065	1.032	8.002	24
31) BL%	0.363	0.2	1.2	0.062	0.248	68.454	24

Pnum/Pname:	Ranges mean+/-	rng	Low	High
1) WBC	16.2	1.4	14.8	17.6
2) RBC	5.12	.18	4.94	5.30
3) HGB	17.1	.5	16.6	17.6
4) HCT	43.5	2.5	41.0	46.0
5) MCV	85.0	4	81.0	89.0
6) MCH	33.4	2	31.4	35.4
7) MCHC	39.3	2.5	36.8	41.8
8) RDW	14.4	2	12.4	16.4
9) PLT	410	45	365	455
10) MPV	6.6	1.5	5.1	8.1
11) NEU	13.1	1.7	11.4	14.8
12) LY	1.7	.6	1.1	2.3
13) MO	0.9	.5	0.4	1.4
14) EOS	0.15	.15	0.00	0.30
15) BAS	0.6	.4	0.2	1.0
16) LUC	0.3	.3	0.0	0.6
17) NEU%	81.1	4	77.1	85.1
18) LY%	10.4	3	7.4	13.4
19) MO%	5.6	3	2.6	8.6
20) EOS%	0.9	.9	0.0	1.8
21) BAS%	3.5	2	1.5	5.5
22) LUC%	2.0	2	0.0	4.0
23) HDW	2.0	1	1.0	3.0
24) LI	2.4	.6	1.8	3.0
25) MPXI	-12.0	8	-20.0	-4.0
26) CHCM	+/- 20.0	1.4	18.6	21.4
27) WBCB	88	10	78	98
28) KX	96	8	88	104
29) KY	10.5	2	8.5	12.5
30) MEX	0.4	.4	0.0	0.8
31) BL%				

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Lot K118L
Low Level
Open Vial Stability Data
Technicon H-1 Instrument
19 Days

Line	ID:		WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	NEU	LY	MO	EOS	BAS	LUC	NEU%	LY%	MO%	EOS%	BAS%	LUC%	HDW	LI	MPXI	WBCB	KX	KY	MNX	BL%	N=:
10/31	W09	OV	2.0	1.95	5.7	14.5	74.3	29.2	39.3	13.7	49	6.7	0.9	0.8	0.1	0.03	0.1	0.1	46.4	41.1	4.2	1.3	5.3	7.0	1.7	2.5	-5.3	3.4	94	96	12.0	4.4	1
11/01	W09	OV	2.0	1.95	5.6	14.5	74.5	28.9	38.8	13.7	52	6.9	1.0	0.8	0.1	0.02	0.1	0.1	47.4	39.1	6.0	0.9	5.4	6.6	1.7	2.3	-7.0	3.3	94	96	9.5	3.5	1
11/02	W09	OV	2.0	1.92	5.6	14.3	74.8	29.5	39.4	13.9	50	6.8	0.9	0.8	0.1	0.03	0.1	0.2	44.3	40.7	5.0	1.5	5.0	8.4	1.6	2.4	-4.4	3.2	96	96	9.0	3.6	1
11/03	W09	OV	1.9	1.94	5.7	14.4	74.3	29.3	39.4	13.8	51	6.7	0.9	0.7	0.1	0.02	0.1	0.2	46.8	38.6	5.6	1.0	5.5	8.0	1.6	2.4	-4.4	3.2	96	98	9.0	4.2	1
11/04	W09	OV	2.1	1.93	5.7	14.2	73.7	29.6	40.2	13.7	55	6.7	0.8	0.9	0.2	0.02	0.1	0.1	41.2	43.3	7.6	1.2	4.2	6.7	1.6	2.3	-7.9	3.3	92	96	9.0	3.7	1
11/07	W10	OV	2.1	1.92	5.7	14.1	73.8	29.8	40.4	13.7	51	6.7	1.0	0.8	0.1	0.02	0.1	0.2	47.2	38.2	6.2	1.1	4.9	7.3	1.6	2.5	-5.3	3.3	94	98	9.0	3.6	1
11/08	W10	OV	2.0	1.95	5.7	14.2	72.5	29.1	40.1	13.9	54	6.7	1.0	0.8	0.1	0.02	0.1	0.1	48.5	39.9	5.3	1.0	5.2	5.3	1.7	2.5	-7.9	3.3	92	96	9.0	4.3	1
11/09	W10	OV	2.2	1.97	5.7	14.5	73.9	29.1	39.4	13.7	56	6.8	1.0	0.8	0.2	0.03	0.1	0.2	46.4	38.5	6.8	1.5	5.1	6.8	1.6	2.5	-11.4	3.3	88	98	9.5	3.5	1
11/10	W10	OV	2.0	1.99	5.7	14.6	73.4	28.6	39.0	13.8	56	7.0	1.0	0.8	0.1	0.02	0.1	0.1	48.2	39.4	5.8	1.2	4.2	5.4	1.6	2.4	-2.6	3.3	98	96	9.0	4.4	1
11/11	W10	OV	2.2	1.99	5.8	14.9	74.9	28.9	38.6	13.7	54	7.2	1.0	0.9	0.2	0.03	0.1	0.2	46.0	38.4	6.7	1.2	4.8	7.7	1.6	2.4	-5.3	3.2	94	96	9.5	4.1	1
11/14	W11	OV	2.1	1.96	5.7	14.1	72.1	29.0	40.3	13.6	55	7.2	1.0	0.8	0.2	0.03	0.1	0.2	47.3	37.2	7.2	1.4	5.1	6.8	1.6	2.5	-4.4	3.4	96	98	9.0	3.9	1
11/15	W11	OV	2.2	1.97	5.7	14.1	71.6	28.8	40.3	13.7	58	7.0	1.0	0.9	0.2	0.02	0.1	0.1	45.4	41.2	8.0	0.9	4.8	4.5	1.6	2.6	-10.5	3.4	90	96	9.0	3.8	1
11/16	W11	OV	2.0	1.94	5.8	14.0	72.2	29.6	41.0	13.7	60	6.9	0.9	0.8	0.2	0.02	0.1	0.2	44.4	38.4	7.6	1.0	5.6	8.6	1.6	2.5	-6.1	3.3	94	100	9.0	3.2	1
11/17	W11	OV	2.1	1.90	5.7	13.8	72.7	30.0	41.2	13.8	57	6.9	1.0	0.8	0.2	0.03	0.1	0.1	49.0	36.6	7.3	1.2	5.2	5.8	1.6	2.6	-7.9	3.3	92	96	9.5	3.9	1
11/18	W11	OV	2.1	1.89	5.7	13.6	72.4	30.3	41.9	13.7	59	6.9	1.0	0.8	0.2	0.03	0.1	0.1	45.3	40.3	7.8	1.4	5.1	5.3	1.7	2.4	-8.8	3.3	92	100	9.0	3.5	1

Num/Name:	Mean	Min	Max	Var	StDev	CV	N
1) WBC	2.066	1.9	2.2	0.008	0.090	4.378	15
2) RBC	1.945	1.89	1.99	0.001	0.029	1.516	15
3) HGB	5.700	5.6	5.8	0.003	0.053	0.938	15
4) HCT	14.253	13.6	14.9	0.108	0.329	2.310	15
5) MCV	73.407	71.6	74.9	1.158	1.076	1.466	15
6) MCH	29.313	28.6	30.3	0.228	0.478	1.630	15
7) MCHC	39.953	38.6	41.9	0.884	0.940	2.353	15
8) RDW	13.740	13.6	13.9	0.007	0.083	0.603	15
9) PLT	54.467	49	60	11.124	3.335	6.123	15
10) MPV	6.873	6.7	7.2	0.029	0.171	2.488	15
11) NEU	0.956	0.8	1.0	0.003	0.056	5.901	15
12) LY	0.813	0.7	0.9	0.002	0.045	5.492	15
13) MO	0.135	0.1	0.2	0.001	0.027	19.820	15
14) EOS	0.025	0.02	0.03	0.000	0.005	20.935	15
15) BAS	0.103	0.1	0.1	0.000	0.009	8.608	15
16) LUC	0.139	0.1	0.2	0.001	0.025	17.677	15
17) NEU%	46.253	41.2	49.0	3.894	1.973	4.266	15
18) LY%	39.393	36.6	43.3	2.982	1.727	4.384	15
19) MO%	6.473	4.2	8.0	1.302	1.141	17.628	15
20) EOS%	1.187	0.9	1.5	0.041	0.203	17.113	15
21) BAS%	5.027	4.2	5.6	0.166	0.408	8.115	15
22) LUC%	6.680	4.5	8.6	1.495	1.223	18.301	15
23) HDW	1.618	1.6	1.7	0.001	0.033	2.026	15
24) LI	2.445	2.3	2.6	0.009	0.094	3.826	15
25) MPXI	-6.613	-11.4	-2.6	6.011	2.452	-37.073	15
26) WBCB	3.299	3.2	3.4	0.004	0.066	2.001	15
27) KX	93.467	88	98	6.552	2.560	2.739	15
28) KY	97.067	96	100	2.210	1.486	1.531	15
29) MNX	9.333	9.0	12.0	0.595	0.772	8.266	15
30) BL%	3.840	3.2	4.4	0.138	0.372	9.684	15

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Lot K118N
Normal Level
Open Vial Stability Data
Technicon H-1 Instrument
19 Days

Line	ID:	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	NEU	LY	MO	EOS	BAS	LUC	NEU%	LY%	MO%	EOS%	BAS%	LUC%	HDW	LI	MPXI	WBCB	KX	KY	MHX	BL%	N=:
10/31	W09 OV	7.0	4.30	13.3	34.5	80.1	30.9	38.6	14.5	213	7.1	5.0	1.3	0.3	0.10	0.3	0.3	71.6	18.5	4.3	1.5	3.6	4.1	1.6	2.6	-4.4	9.4	96	92	9.0	2.5	1
11/01	W09 OV	7.0	4.29	13.2	34.0	79.3	30.8	38.8	14.6	207	7.1	5.0	1.4	0.3	0.08	0.3	0.3	70.4	20.2	4.3	1.1	3.5	3.9	1.6	2.5	-1.8	9.2	98	90	9.0	2.5	1
11/02	W09 OV	6.8	4.32	13.2	34.1	79.0	30.7	38.8	13.9	206	7.1	4.9	1.3	0.2	0.11	0.2	0.3	71.6	19.0	3.3	1.6	3.4	4.5	1.6	2.5	0.9	9.1	100	92	12.0	2.4	1
11/03	W09 OV	6.8	4.32	13.2	34.0	78.6	30.5	38.8	14.0	216	7.0	4.8	1.3	0.3	0.11	0.2	0.3	71.3	19.3	3.7	1.6	3.6	4.2	1.6	2.5	-1.8	9.1	98	90	9.0	2.2	1
11/04	W09 OV	7.1	4.27	13.2	33.6	78.6	31.0	39.5	14.5	213	6.9	4.8	1.3	0.4	0.09	0.3	0.5	67.4	18.9	5.8	1.3	3.5	6.6	1.6	2.5	-3.5	9.1	96	90	9.0	2.3	1
11/07	W10 OV	6.6	4.18	13.0	32.6	77.9	31.1	39.9	13.9	223	7.1	4.6	1.4	0.3	0.08	0.2	0.2	69.9	21.4	4.0	1.3	3.6	3.5	1.6	2.5	-3.5	9.5	96	92	10.0	2.2	1
11/08	W10 OV	6.8	4.27	13.1	33.1	77.6	30.7	39.6	14.6	212	7.1	4.9	1.4	0.3	0.10	0.2	0.2	71.7	20.0	3.6	1.5	3.5	3.3	1.6	2.4	-4.4	9.4	96	92	9.0	2.8	1
11/09	W10 OV	6.9	4.42	13.3	34.4	77.9	30.0	38.5	13.9	206	7.1	5.1	1.3	0.2	0.09	0.2	0.3	73.3	18.7	3.2	1.2	3.3	3.6	1.5	2.4	-7.0	9.2	94	92	9.0	2.3	1
11/10	W10 OV	6.8	4.31	13.3	33.9	78.8	30.8	39.1	14.5	210	7.2	4.9	1.3	0.3	0.09	0.3	0.2	72.2	18.9	4.1	1.3	3.7	3.5	1.5	2.3	-4.4	9.3	96	94	10.0	2.3	1
11/11	W10 OV	7.1	4.32	13.2	34.2	79.2	30.5	38.5	14.5	212	7.1	4.9	1.4	0.4	0.09	0.3	0.3	68.7	20.4	5.5	1.3	3.5	4.1	1.5	2.2	-0.9	9.1	100	96	9.0	2.1	1
11/14	W11 OV	6.9	4.26	13.3	33.2	77.9	31.2	40.0	14.5	207	7.1	4.9	1.4	0.3	0.09	0.2	0.2	71.0	20.4	3.7	1.3	3.2	3.6	1.5	2.6	0.9	9.2	100	90	9.0	2.1	1
11/15	W11 OV	7.3	4.42	13.5	33.9	76.7	30.4	39.7	14.4	215	7.1	5.2	1.4	0.4	0.11	0.3	0.2	71.5	19.2	5.0	1.6	3.7	2.8	1.6	2.5	-0.9	9.4	98	96	9.5	2.4	1
11/16	W11 OV	7.2	4.33	13.3	33.3	76.8	30.6	39.9	14.0	215	7.1	5.1	1.3	0.4	0.10	0.3	0.3	70.7	18.5	5.4	1.4	4.2	4.0	1.6	2.5	1.8	9.3	102	92	9.5	2.1	1
11/17	W11 OV	7.1	4.20	13.3	32.2	76.7	31.5	41.1	14.0	222	7.3	5.0	1.4	0.4	0.08	0.2	0.3	70.1	19.1	5.7	1.2	3.3	3.9	1.6	2.5	0.9	9.2	100	90	9.5	2.2	1
11/18	W11 OV	7.2	4.26	13.3	32.7	76.6	31.2	40.8	13.9	215	7.2	5.2	1.3	0.4	0.10	0.3	0.2	71.9	18.5	5.1	1.3	3.4	3.1	1.6	2.6	0.9	9.4	100	92	10.0	2.4	1

Pnum/Pname:	Mean	Min	Max	Var	StDev	CV	N
1) WBC	6.965	6.6	7.3	0.042	0.204	2.926	15
2) RBC	4.298	4.18	4.42	0.004	0.066	1.529	15
3) HGB	13.247	13.0	13.5	0.013	0.113	0.850	15
4) HCT	33.540	32.2	34.5	0.487	0.698	2.079	15
6) MCV	78.113	76.6	80.1	1.101	1.021	1.307	15
7) MCH	30.793	30.0	31.5	0.142	0.377	1.224	15
8) MCHC	39.440	38.5	41.1	0.661	0.813	2.062	15
9) RDW	14.247	13.9	14.6	0.090	0.300	2.104	15
11) PLT	212.800	206	223	27.314	5.226	2.456	15
13) MPV	7.107	6.9	7.3	0.000	0.000	1.244	15
17) NEU	4.935	4.6	5.2	0.026	0.162	3.278	15
18) LY	1.349	1.3	1.4	0.003	0.053	3.936	15
19) MO	0.311	0.2	0.4	0.005	0.068	21.915	15
21) EOS	0.095	0.08	0.11	0.000	0.011	11.198	15
22) BAS	0.247	0.2	0.3	0.000	0.019	7.763	15
23) LUC	0.272	0.2	0.5	0.004	0.063	23.260	15
24) NEU%	70.887	67.4	73.3	2.116	1.454	2.052	15
25) LY%	19.400	18.5	21.4	0.766	0.875	4.511	15
26) MO%	4.447	3.2	5.8	0.801	0.895	20.130	15
28) EOS%	1.367	1.1	1.6	0.025	0.159	11.624	15
29) BAS%	3.533	3.2	4.2	0.055	0.235	6.652	15
30) LUC%	3.913	2.8	6.6	0.753	0.868	22.169	15
31) HDW	1.565	1.5	1.6	0.001	0.025	1.582	15
32) LI	2.470	2.2	2.6	0.012	0.109	4.419	15
33) MPXI	-1.813	-7.0	1.8	6.917	2.630	-145.03	15
37) WBCB	9.259	9.1	9.5	0.021	0.146	1.572	15
38) KX	98.000	94	102	5.143	2.268	2.314	15
39) KY	92.000	90	96	4.000	2.000	2.174	15
40) MHX	9.500	9.0	12.0	0.643	0.802	8.440	15
42) BL%	2.320	2.1	2.8	0.036	0.190	8.178	15

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Lot K118H
High Level
Open Vial Stability Data
Technicon H-1 Instrument
16 Days

Line	ID:	WBC	RBC	HGB	HCT	MCV	MCH	MCHC	RDW	PLT	MPV	NEU	LY	MO	EOS	BAS	LUC	NEU%	LY%	MO%	EOS%	BAS%	LUC%	HDW	LI	MPXI	WBCB	KX	KY	MHX	BL%	N=:
11/03	W09 OV	15.2	5.03	16.9	42.6	84.7	33.6	39.7	13.7	403	7.4	12.0	2.1	0.5	0.12	0.5	0.4	78.8	14.0	3.6	0.8	3.1	2.9	1.8	2.6	-7.0	19.1	94	90	9.0	1.4	1
11/04	W09 OV	15.4	5.10	16.9	43.2	84.6	33.1	39.2	13.7	413	7.3	12.5	2.0	0.4	0.14	0.4	0.3	80.9	13.1	2.9	0.9	2.7	2.2	2.4	2.6	-7.0	20.1	94	90	9.5	1.1	1
11/07	W10 OV	15.5	5.08	16.9	42.8	84.3	33.3	39.5	13.7	402	7.5	12.3	2.1	0.6	0.10	0.5	0.4	79.5	13.5	3.6	0.7	2.9	2.7	2.5	2.6	-7.0	19.7	94	90	12.0	1.3	1
11/08	W10 OV	15.3	5.06	17.0	42.3	83.7	33.5	40.0	13.7	407	7.4	12.3	2.0	0.5	0.13	0.5	0.4	80.1	13.3	3.3	0.9	3.1	2.7	2.7	2.5	-7.0	20.1	94	89	14.0	1.3	2
11/09	W10 OV	15.7	5.09	17.0	42.9	84.3	33.4	39.6	13.7	421	7.5	12.6	2.2	0.5	0.13	0.5	0.4	79.9	13.9	3.0	0.8	2.9	2.4	2.5	2.6	-7.0	19.7	94	92	12.0	1.1	1
11/10	W10 OV	15.4	5.11	17.0	43.7	85.4	33.2	38.9	14.3	437	7.4	12.5	2.0	0.4	0.11	0.5	0.4	81.1	13.0	2.7	0.7	3.0	2.5	2.8	2.6	-10.5	19.7	90	90	12.0	1.2	1
11/11	W10 OV	15.8	5.10	17.0	44.0	86.3	33.3	38.6	14.3	422	7.6	12.5	2.1	0.6	0.12	0.4	0.4	79.3	13.5	3.9	0.8	2.7	2.5	2.3	2.8	-4.4	20.0	96	90	12.0	1.1	1
11/14	W11 OV	16.0	4.99	17.1	42.4	84.9	34.2	40.3	14.4	406	7.4	12.7	2.2	0.6	0.14	0.4	0.4	79.1	13.6	3.8	0.9	2.5	2.6	2.0	2.5	-4.4	19.9	96	88	12.0	1.1	1
11/15	W11 OV	15.9	5.12	16.9	42.5	83.1	33.1	39.9	13.8	411	7.5	12.7	2.1	0.6	0.12	0.5	0.3	80.1	13.2	3.8	0.8	2.9	2.0	2.9	2.5	-4.4	19.8	96	86	12.0	1.3	1
11/17	W11 OV	15.7	5.02	17.3	42.0	83.7	34.5	41.3	13.8	419	7.5	12.6	2.1	0.5	0.13	0.5	0.4	80.3	13.5	2.9	0.8	2.8	2.5	2.1	2.6	-4.4	20.3	96	86	12.0	1.1	1
11/18	W11 OV	16.1	4.96	17.3	41.6	84.1	34.9	41.5	13.8	429	7.4	12.9	2.1	0.6	0.14	0.5	0.4	80.1	13.3	3.6	0.8	3.0	2.2	3.0	2.5	-5.3	20.5	94	90	9.5	1.0	1

Param/Frame:	Mean	Min	Max	Var	StDev	CV	N
WBC	15.601	15.2	16.1	0.083	0.289	1.852	12
RBC	5.059	4.96	5.12	0.003	0.053	1.041	12
HGB	17.017	16.9	17.3	0.022	0.147	0.862	12
HCT	42.692	41.6	44.0	0.475	0.689	1.615	12
MCV	84.[illegible]	83.1	86.3	0.753	0.868	1.028	12
MCH	33.[illegible]	33.1	34.9	0.348	0.590	1.744	12
MCHC	39.[illegible]	38.6	41.5	0.749	0.865	2.171	12
RDW	13.[illegible]	13.7	14.4	0.076	0.276	1.986	12
PLT	414.667	402	437	123.879	11.130	2.684	12
MPV	7.442	7.3	7.6	0.008	0.090	1.210	12
NEU	12.475	12.0	12.9	0.059	0.243	1.945	12
LY	2.095	2.0	2.2	0.004	0.064	3.050	12
MO	0.523	0.4	0.6	0.008	0.090	17.156	12
EOS	0.126	0.10	0.15	0.000	0.015	11.961	12
BAS	0.449	0.4	0.5	0.000	0.022	4.883	12
LUC	0.367	0.3	0.4	0.001	0.037	9.443	12
NEU%	79.933	78.8	81.1	0.517	0.719	0.900	12
LY%	13.433	13.0	14.0	0.106	0.326	2.424	12
MO%	3.358	2.4	4.1	0.301	0.548	16.332	12
EOS%	0.808	0.7	1.0	0.008	0.090	11.138	12
BAS%	2.883	2.5	3.1	0.032	0.180	6.245	12
LUC%	2.483	2.0	2.9	0.067	0.259	10.421	12
HDW	2.471	1.8	3.0	0.122	0.350	14.150	12
LI	2.542	2.5	2.8	0.007	0.085	3.298	12
MPXI	-6.283	-10.5	-4.4	3.274	1.809	-28.798	12
WBCB	19.903	19.1	20.5	0.148	0.384	1.931	12
KX	94.333	90	96	2.788	1.670	1.770	12
KY	89.167	86	92	3.242	1.801	2.019	12
MHX	11.333	9.0	12.0	1.470	1.212	10.697	12
BL%	1.183	1.0	1.4	0.014	0.119	10.085	12

Questions? Contact FDA/CDRH/OCE/DIDM-8418

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