K993375

DEC 20 1999

Abbreviated 510(k)
CDS LTX-Control

Revision C 12/08/99

I. Device Description

Common Names: Latex Calibrator, Latron® Calibrator
Class: II
Classification Panel: Hematology (81)

Product Codes: KRY Calibrator for Platelet Counting
KSA Calibrator for Red-Cell and White-Cell Counting
KRX Calibrator for Cell Indices

Regulation Numbers:
21 CFR 864.8150
21 CFR 864.8165
21 CFR 864.8175
21 CFR 864.8185

II. Indication for Use Statement

Hematology (81) The CDS LTX-Control for red cell, white cell, and platelet counting is a device that resembles red cells, white cells, and platelets, and is used to validate the electronic calibration of the volume, conductivity and light scatter parameters on Coulter® MAXM®, STKS® and GEN•S® instruments intended to count red cells, white cells, and platelets. It is a suspension of uniform particles whose shape, size, and concentration and other characteristics have been precisely and accurately determined.

III. Labeling

Samples of proposed labeling for CDS LTX-Primer and CDS LTX-Control are attached.

IV. Summary Report

NOTE: This product will not perform properly if stored at temperatures above 30°C. Best results are obtained when the product is stored at 2 - 8°C (34 - 46°F).

a. The protocol used for stability testing includes accelerated testing at 37°C and 50°C, and real-time at ambient room temperature. Stability testing was performed at ambient room temperature, 37°C and 50°C using pilot production material that was packaged in final primary packaging for both CDS LTX-Control. This material was compared with fresh material and other commercial controls (**Latron** and **Latron Primer**, Beckman Coulter Inc.) using a calibrated Coulter® Model STKS analyzer system at daily, weekly or monthly intervals, depending on the

storage temperature. The product stability-dating interval is revised upward each month, upon successful completion of the testing. Acceptance criteria indicates calibration result must be within ±3% of the previous value from the same lot of material.

b. A well-calibrated Coulter Model STKS analyzer is purged with LTX-Primer for not less than two "start up" cycles, in order to prime all fluid pathways. The LTX-Primer serves to coat all of the internal fluid surfaces, particularly plastic ones, to prevent the LTX particles from sticking inside the analyzer. The LTX-Control is aspirated and analyzed repetitively for 31 cycles, and all data is recorded. The first cycle is discarded, and the mean result is calculated for the remaining 30 replicates:

$$(n_2 + n_3 + \ldots n_{31}) \div 30 = \text{mean value}$$

An alternative "running" method for assay is used for some lots. The above procedure is followed, except that the LTX-Control is analyzed once or more per day until 31 assay cycles have been reached. The mean result is calculated as above.

The analyzer system is validated by repetitive analysis of a competitive material (**Latron** and **Latron Primer**, Beckman Coulter Inc.).

c. A Coulter Model STKS analyzer is calibrated using a standard commercial calibration material and validated by assaying at least three levels of commercial control materials for three cycles each. The three values from each level are averaged and the mean value is compared to the reference value assigned by the manufacturer. A deviation of ±3% is the accepted range for results. The LTX-Primer is then used to prepare the system fluid pathways by at least two "start up" cycles, then the CDS LTX-Control material is aspirated and analyzed at least 31 times, and the replicate data is recorded. The first set of values is discarded and the remaining 30 values are statistically calculated as a normal distribution. A t-test of the mean is also performed to evaluate the distribution of results.

Experience with the CDS LTX-Control has revealed that the Light Scatter parameter requires three to five days of aging in the final solution to reach a stable value. Assay values for a given lot number of CDS LTX-Control are therefore assigned five days after manufacture and packaging (indicated by the vertical blue line on **Charts 1** and **2**.)

d. There is no standard reference material specifically evaluated for assignment of flowcell calibration values for the Coulter Model STKS

analyzer system. Repetitive analysis of commercial competitive material from the instrument system's manufacturer is statistically compared to repetitive analysis of CDS LTX-Control as an indication of calibration parallelism with the manufacturer's intended system performance.

e. Performance of the CDS LTX-Control is compared statistically with performance of an NIST-traceable primary particle standard made from the same chemical material and suspended in the same LTX-Primer solution. The NIST-traceable primary standard is assayed by the Coulter Model STKS 11 times, the first value is discarded and the remaining 10 values are used to calculate a mean value for each of the calibrateable channels. CDS LTX-Control assay is then compared to the primary standard. No correction is made for the stated difference in particle sizes, since both particle assays lie within the precision range stated for each particle.

f. The assigned values for the CDS LTX-Control are compared to results obtained from normal human blood specimens; values assigned should be within $\pm 10\%$ of the mean average of the normal sample results.

g. The methodology effectively transfers the known size of the NIST traceable latex standard to the secondary CDS LTX-Control. This standard is then used to assure the proper positioning of the laser for the normally accepted detection of cellular elements found in human blood cells.

Data Summary

1. Data tables for two lot numbers of CDS LTX-Control, both prepared from a single lot number of polymer particles, but resuspended and diluted in different batches of LTX-Primer solution are presented as **Tables I.** and **II.**

2. The analysis of the NIST-traceable primary particle standard is shown in **Table III.**

3. These lot numbers were analyzed repetitively over a period of about ninety (90) days, and both show stability over the period from Day 3 through the end of the data tables. Occasional small deviations appear in the data and are correlated to problems with the instrument system. Recalibration to the Beckman Coulter **Latron®** Control standard corrected the values in every case.

4. The Light Scatter value (S) is the parameter that is most sensitive to changes in the analyzer system, so it is used to monitor changes in the CDS LTX-Control material. **Chart 1** shows the value trend for the Light Scatter parameter for trial lot 503. The upper and lower limit lines represent ± 3% of the mean assay value and are the acceptable upper and lower limits of usage in the analyzer system. **Chart 2** shows the same results for trial lot 504.

   NOTE: The out-of-range point circled in red on both charts has been traced to an instrument malfunction. After servicing, the analyzer again produced values consistent with previous Light Scatter results. The Volume and Conductivity results were unaffected.

Checklist and 510(k) References

1. Proprietary and Established Name:

   CDS LTX-Control Latex Particle Suspension

   CDS LTX-Primer Priming Solution

2. Intended Use:

   CDS LTX-Control is used to validate the volume, conductivity and light scatter parameters on COULTER® MAXM, STKS and GEN•S instruments. CDS LTX-Primer is used only to prepare the instrument fluid pathways immediately prior to CDS LTX-Control measurements, and plays no role in the recovery of test results.

3. Summary and Explanation:

   Accurate differential and reticulocyte measurements on COULTER MAXM, STKS and GEN•S instruments are measured by monitoring the consistent performance of volume, conductivity and light scatter, using a particle of uniform size with appropriate light scattering characteristics. CDS LTX-Control validates the stability of electrical processing and fluidic flow rate systems used to measure volume, conductivity and light scatter channels.

4. Test Principle:

   CDS LTX-Control is supplied as ready-to-use latex particles in a buffered suspension fluid. The particles pass through the flow cell producing characteristic electrical signals that are measured as volume,

conductivity and light scatter for quality monitoring of the previously mentioned COULTER instruments.

5. Description of the calibrator material:

Matrix base - aqueous, buffered, bacteriostatic and fungistatic medium containing a surfactant.

Constituents - alkali metal salts, detergents, antimicrobial materials and polymer beads of known size.

Appropriate standardization/Relationship/Traceability: The beads are compared to NIST-calibrated beads of known size, under the conditions of use within the applicable hematology analyzer systems. Dual analyses of NIST-calibrated beads versus CDS LTX-Control are performed for each lot.

Warnings and Precautions: Do not store CDS LTX-Control at temperatures above 30°C. Do not freeze CDS LTX-Control. Keep bottles of CDS LTX-Control tightly capped when not in use.

Appropriate Testing of Human Source Material: Not applicable.

For *In Vitro* Diagnostic Use.

Assigned Values and Value Assignment Process:
A well-calibrated Coulter Model STKS analyzer is purged with CDS LTX-Primer for not less than two "start up" cycles, in order to prime all fluid pathways. The LTX-Primer serves to coat all of the internal fluid surfaces, particularly plastic ones, to prevent the LTX particles from sticking inside the analyzer. The LTX-Control is aspirated and analyzed repetitively for 31 cycles, and all data is recorded. The first cycle is discarded, and the mean result is calculated for the remaining 30 replicates:

$$(n_2 + n_3 + \ldots n_{31}) \div 30 = \text{mean value}$$

Standard deviation and percent coefficient of variation are also calculated by standard statistical means. The analyzer system is validated by repetitive analysis of a competitive material (**Latron** and **Latron Primer**, Beckman Coulter Inc.).

Storage Instructions and Stability: CDS LTX-Control and CDS LTX-Primer should be stored at 18-30°C (64-86°F). Do not store CDS LTX-Control at temperatures above 30°C. DO NOT FREEZE. Opened

bottles are guaranteed stable for 30 days after opening, when package directions are followed. Be certain that CDS LTX-Control is at ROOM TEMPERATURE before use. Keep bottles tightly capped when product is not being used.

Indications of Deterioration: Inability to recover CDS LTX-Control values identified in the ranges on the EXPECTED RESULTS chart may indicate product instability or deterioration due to improper storage, handling or contamination. Verify that the product has not exceeded its opened or closed bottle expiration date. If the product has been frozen or exposed to temperatures outside of the recommended temperature range, it may not recover the assigned values. Also, bottles contaminated with debris may exhibit more than one population, resulting in increased Coefficients of Variation. Should problems arise, open another bottle of CDS LTX-Control. If the problem persists, contact your Clinical Diagnostic Solutions representative, our Technical Service Department or our Customer Service Department at **800-453-3328**.

Directions for Use: Consult the appropriate COULTER MAXM, STKS and GEN•S Product Manuals for the proper instrument operating instructions.

1. Perform instrument startup according to the specific COULTER Manual.
2. Configure the instrument for daily quality control for latex particle analysis according to the appropriate Product Manual.
3. Prepare instrument sample line with CDS LTX-Primer according to the package insert and the appropriate Product Manual. Verify that the count result is acceptable.
4. Gently mix a room temperature bottle of CDS LTX-Control by inverting five (5) to eight (8) times; ensure there is no foaming.
5. Aspirate CDS LTX-Control and remove bottle when the audible "Beep" sound occurs.
6. If your instrument does not have a self-cleaning sample aspirating probe, wipe the probe with a dry, absorbent, lint-free tissue.
7. Examine the Mean Channel and Coefficient of Variation results for volume, conductivity and light scatter. Compare the results to those of the EXPECTED RESULTS chart. Record and/or plot these values in the instrument log. These functions are performed automatically for you on the STKS, MAXM and GEN•S instruments.

Limitations: None are reported.

Bibliography/References: No specific references other than instrument Product Manuals.

Name and Place of Manufacture: **Clinical Diagnostic Solutions, Inc.**
1660 N. W. 65th Avenue, Suite 2
Plantation, FL 33313

Date of Labeling Revision: July 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 20 1999

Mr. Colin Aldersley
Director of Regulatory Affairs
Clinical Diagnostic Solutions, Inc.
1660 NW 65th Avenue, Suite 2
Plantation, Florida 33313

Re: K993375
Trade Name: CDS LTX Control Latex Particle Suspension and Primer™
Regulatory Class: II
Product Code: KRX, KRZ, KRY, KSA
Dated: October 6, 1999
Received: October 7, 1999

Dear Mr. Aldersley:

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 (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) 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. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, 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 sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K993375

Device Name: CDS LTX-Control Latex Particle Suspension

Indications for Use:

CDS LTX-Control Latex Particle Suspension is intended to serve as a calibration standard for the d.c. impedance, r.f. impedance and optical light scatter parameters of the VCS module of Coulter® Models STKS, MAXM and Gen•S Hematology Analyzer systems. Models STKS and MAXM analyzers equipped with 5-part differential capability only require aspiration of the CDS LTX-Control Latex Particle Suspension through the secondary mode aspiration inlet with the analyzer set to function F55. STKS and Gen•S analyzers equipped with 5-part differential and reticulocyte capability require aspiration of the CDS LTX-Control Latex Particle Suspension through the secondary mode aspiration inlet with the analyzer set to function F57.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993375

Prescription Use ✓ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)