510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

K102400

B. Purpose for Submission:

To obtain a Substantial Equivalence determination for the Syphilis Health Check Treponemal Antibody Test

C. Measurand:

Antibodies to *Treponema pallidum* (*T. pallidum)*

D. Type of Test:

A qualitative rapid membrane immunochromatographic assay

E. Applicant:

Diagnostics Direct, LLC

F. Proprietary and Established Names:

Syphilis Health Check Treponemal Antibody Test; Rapid immunochromatographic membrane assay, *Treponema pallidum*

G. Regulatory Information:

1. Regulation section:

   21 CFR § 866.3830, *Treponema pallidum* treponemal test reagents

2. Classification:

   Class II

3. Product code:

   LIP - Enzyme linked immunoabsorption assay, Treponema pallidum

4. Panel:

   Microbiology (83)

H. Intended Use:

1. Intended use:

   Syphilis Health Check is a qualitative rapid membrane immunochromatographic assay for the detection of *Treponema pallidum* (syphilis) antibodies in human whole blood, serum or plasma. This product can be used as an initial screening test or in conjunction with a non-treponemal laboratory test and clinical findings to aid in the diagnosis of syphilis infection. This test is not intended for use in screening blood or plasma donors.

2. Indications for use:

   Syphilis Health Check is a qualitative rapid membrane immunochromatographic assay for the detection of *Treponema pallidum* (syphilis) antibodies in human whole blood, serum or plasma. This product can be used as an initial screening test or in conjunction with a non-treponemal laboratory test and clinical findings to aid in the diagnosis of syphilis infection. This test is not intended for use in screening blood or plasma donors.

3. Special condition for use statement:

   For prescription use only.

4. Special instrument requirements:

   Not applicable.

I. Device Description:

Syphilis Health Check Treponemal Antibody Test method employs a unique combination of anti-human immunoglobulins gold conjugate and highly purified TP recombinant proteins to specifically detect anti-TP antibodies.

J. Substantial Equivalence Information:

1. Predicate device name:

   - Trep- Chek Treponemal Antibody EIA

2. Predicate 510(k) number:

   - K001552

1. Comparison with predicate:

Similarities		
Item	Device	Predicate
Intended Use	Syphilis Health Check is a qualitative rapid membrane immunochromatographic assay for the detection of *Treponema pallidum* (syphilis) antibodies in human whole blood, serum or plasma. This product can be used as an initial screening test or in conjunction with a non-treponemal laboratory test and clinical findings to aid in the diagnosis of syphilis infection. This test is not intended for use in screening blood or plasma donors.	The Phoenix Bio-Tech Corp. Syphilis Trep-Chek Test Kit is a confirmatory immunoassay for the qualitative detection of Treponema pallidum IgG antibodies in human serum or plasma. This product is not cleared (approved) by the U.S. Food and Drug Administration (FDA) for use in screening blood or plasma donors.
Assay type	Enzyme labeled, immunoassay	Enzyme labeled, immunoassay
Analyte Measured	Human IgG	Human IgG

Differences		
Item	Device	Predicate
Sample Dilution	1:21 in SAVe Diluent	1:20 in phosphate buffer based diluent
Detection Method	Fluorescent	Colorimetric

Differences		
Item	Device	Predicate
Scale	Intra-Well Calibration determines a unit value for each sample from the regression curve	Calculate the index value of unknown samples by comparing their OD to the cut off OD
Sample Dilution	1:21 in SAVe Diluent	1:20 in phosphate buffer based diluent
Specimen Tested	Human Serum	Human Serum or plasma
Calibration	Includes Intra-Well Calibration that provides a separate calibration curve for every sample	Includes Calibrator (human serum)
Cut-Offs	Negative is < 100, Positive is > 120 and Equivocal is 100-120 AU/mL	Negative is <= 0.90, Positive is >= 1.10 and Equivocal is 0.90 - 1.09

K. Standard/Guidance Document Referenced:

- CLSI EP07-A2: Interference Testing in Clinical Chemistry
- CLSI EP5: Evaluation of Precision Performance of Clinical Chemistry Devices-Second Edition
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, May 11, 2005

L. Test Principle:

Specific, recombinant treponemal antigens are immobilized on the membrane. Patient samples or controls are added to the sample well, followed by a buffer, and as the sample flows through the absorbent device, the human immunoglobulins bind to the antigens forming an antigen-antibody complex. The antigen-antibody complex further reacts with a unique combination of colloidal gold conjugated Protein A and anti-human immunoglobulins producing a pink-rose colored band that can be read visually indicating antibody is present in the patient's sample. A separate Control Line indicates reagents are functioning correctly.

M. Performance Characteristics:

1. Analytical performance:

a. Precision/Reproducibility:

To demonstrate the reproducibility of the Syphilis Health Check Treponemal Antibody Test, the assay was evaluated at three study sites using trained technicians for within-Run and between day reproducibility using a panel of pooled samples. Each testing site conducted reproducibility studies using a supplied panel ranging from non-reactive to highly reactive, i.e. one nonreactive, one high (borderline) nonreactive, one low (borderline) reactive, one moderate reactive, and two mid-high to high reactive in addition to the kit controls. Each site ran these panel member solutions for at least 10 days total spread throughout the study period. A second study included low (borderline) reactive and moderate reactive samples, each site ran these panel member solutions for at least 5 days, twice per day. Each site performed one Within-Run assay by each of the operators each run for 10 times on one day. The following testing results were obtained,

Intra-Run

Panel D (Borderline Reactive)

	Positive	Negative	Expected	% Agree	Discrepant
Site 1 (2 operators)	57	3	60 positive	95.0	3
Site 2 (2 operators)	58	2	60 positive	96.7	2
In-house (2 operators)	59	1	60 positive	98.3	1

Panel E (Borderline Nonreactive)

	Positive	Negative	Expected	% Agree	Discrepant
Site 1	1	59	60 negative	98.3	1
Site 2	2	58	60 negative	96.7	2
In-House	0	60	60 negative	100.0	0

Inter-Day (5 days)

Panel D (Borderline Reactive)

	Positive	Negative	Expected	% Agree	Discrepant
Site 1 (2 operators)	57	3	60 positive	95.0	3
Site 2 (2 operators)	58	2	60 positive	96.7	2
In-house (2 operators)	57	3	60 positive	95.0	3

Panel E (Borderline Nonreactive)

	Positive	Negative	Expected	% Agree	Discrepant
Site 1	2	58	60 negative	96.7	2
Site 2	2	58	60 negative	96.7	2
In-House	1	59	60 negative	98.3	1

Inter-Lot

Studies were performed to demonstrate the Inter-Lot assay reproducibility of Syphilis Health Check Treponemal Antibody Test. The Inter-Lot study used four dilutions of a positive pool and negative sera samples. These five samples were run in duplicate on 5 different lots to demonstrate lot-to-lot reproducibility run on the same day by the same technician.

The following table demonstrates the reproducibility of the Syphilis Health Check Treponemal Antibody Test over 5 lots of kits.

Dilution	Results after 10 min.					
	Expected results	Lot I	Lot II	Lot III	Lot IV	Lot V
Negative serum	-	-	-	-	-	-
$1/10^4$	-	-	-	-	-	-
$1/10^3$	+/-	+/-	+/-	+/-	+/-	+/-
$1/10^2$	+	+	+	+	+	+
1/10	+	+	+	+	+	+

Results from the reproducibility studies are acceptable.

b. Linearity/assay reportable range:

Not applicable.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Not applicable.

d. Detection limit:

Not applicable.

e. Analytical specificity:

Cross-Reactivity Study

To test for possible cross-reactivity, panels of samples were obtained to evaluate potential interference from different disease conditions confirmed positive and containing different concentrations of potentially cross-reactive antibodies and were analyzed with the Syphilis Health Check test. Out of 151 (138 were Males) prospectively collected drug users, 11 (7%) were syphilis positive by reference methods and Syphilis Health Check, with two additional samples positive for Syphilis Health Check. Two samples from Lyme disease and HSV showed a positive result with Syphilis Health Check but could not be confirmed. One sample each from CMV positive and heterophile positive patients were Syphilis Health Check positive, but non-reactive by reference methods. Two HPV patients were Syphilis Health Check positive with one confirmed by reference methods. Two co-infected Chlamydia/GC patients were Syphilis Health Check and one confirmed positive by TPPA. The number of disease condition categories and reactive results obtained is listed in the following table.

Cross-reactor	Number	# positive by Syphilis Health Check	# positive by reference method(s)
Self-reported Drug Users	151	13	11
ANA Positive	24	0	
RF Positive	40	0	
U.S. Lyme Disease IgG & IgM	25	1	Not confirmed
HSV	24	1	Not confirmed
CMV	10	2	1
EBV	21	0	
HAV	25	0	
HIV 1 & 2	14	1	1
HTLV	14	1	1
Heterophile	32	1	0
HCV	24	1	1
Anti-HBs	25	2	2
Other STD - GC, Chlamydia, HPV, Trichomonas,	78	4	2

Syphilis Positive HIV / HCV / HBV Patients :

A series of 13 patients EDTA Plasma samples obtained from a blood center were identified as screened RPR positive in patients that were also confirmed positive for HIV, HCV and/or Hepatitis B virus. Three of these patients were further identified as previously testing positive for syphilis and treated at that time. All of the samples were tested with TPPA and Syphilis Health Check to evaluate syphilis reactivity. All 13 samples were positive for RPR, TPPA, and Syphilis Health Check.

To further evaluate the influence of HIV on Syphilis Health Check results, a series of 24 banked serum containing high levels of viral load for HIV were tested with Syphilis Health Check. The HIV positive patient samples were purchased from a commercial serum supplier that was known to be RPR and/or Treponema positive. The samples were tested by an outside lab with the Syphilis Health Check test to assess reactivity. Six of these samples were Nonreactive by RPR but reactive with TPHA. One sample was RPR positive, but TPHA nonreactive. All 24 samples were Syphilis Health Check Positive.

Pregnant Women:

A series of sixty-nine (69) pregnant female samples were purchased from a vendor that had known trimester, age, and ethnicity. An additional set of 93 pregnant women serum samples were obtained from a commercial source that were identified as syphilis positive by RPR screening and further tested with TPPA and Syphilis Health Check. Age and trimester were known, but ethnicity was not identified. Three samples out of the 162 total samples were RPR low positive but nonreactive by the treponemal reference method.

Pregnant Women Summary

		RPR			TPPA		
		Pos	neg	Total	Pos	neg	Total
Syphilis Health Check	Pos	91	0	91	94	0	94
	Neg	3	68	71	0	68	68
	Total	94	68	162	94	68	162

Percent Positive Agreement = 96.8% (95% C.I.= 91.0 - 99.3%) 100.0% (95% C.I.= 96.2 - 100%)
Percent Negative Agreement = 100.0% (95% C.I.= 94.7 - 100%) 100.0% (95% C.I.= 94.7 - 100%)
Percent Overall Agreement = 98.1% (95% C.I.= 94.7 - 99.6%) 100.0% (95% C.I.= 97.7 - 100%)

The results obtained from the cross reactive study are acceptable.

Interference Testing

Interference testing was conducted using serum. Concentrates of the compounds were prepared and diluted to multiple concentrations into eight sera with different levels of syphilis reactivity. The following results were obtained:

Hemoglobin: No effect was observed up to 1000 mg/dL of hemoglobin;
Bilirubin (total): No effect was observed up to 40 mg/dL of total bilirubin;
Triglycerides: No effect was observed up to 3000 mg/dL of triglycerides.
Cholesterol (total): No effect was observed up to 400mg/dL of cholesterol
Albumin: No effect was observed up to 1000 mg/dL of albumin
Gamma-globulin: No effect as observed up to 5000 mg/dL of gamma-globulin

The results obtained from the interference study are acceptable.

f. Assay cut-off:

The Master Cutoff of the assay was determined by calibrating against a panel of confirmed uninfected patient samples and borderline treponemal positive samples diluted to assess the imprecision around the cut-off of the assay. The samples obtained were commercially available serum "standardized" against the WHO Reference Material.

Negative
One colored band appears in the control area.

Positive
In addition to the control band, a distinguishable band also appears in the test area.

Inconclusive
If there is no distinct color band visible in the test and control areas, the test is inconclusive. In this case, repeat the test.

2. Comparison studies:

   a. Method Comparison with Predicate:

   Not applicable.

   b. Matrix comparison:

   Not applicable.

3. Clinical Studies:

   a. Clinical Sensitivity:

   In order to evaluate the performance of the Syphilis Health Check test a series of 880 patient samples were obtained from prospective study sites and 412 frozen retrospective samples purchased from outside commercial vendors and blood centers. In addition, a series of 164 clinically diagnosed samples were obtained that were known primary, secondary, and latent both treated and untreated. The total of 1292 known retrospective samples (576) and prospectively collected (880) patient samples were used to demonstrate the performance of the Syphilis Health Check test to Non-treponemal RPR and other treponemal tests.

   Prospective Studies were conducted at five clinical study sites which compared the Syphilis Health Check to RPR, a non-treponemal test, and treponemal tests such as TPPA, TPHA, or ELISA, using specimens from patients coming into four STD clinics and one hospital clinic. The patients enrolled in the study were identified by medical associates as suspected positive for syphilis and exhibiting symptoms.

   Initial evaluations were performed at a university clinic and a hospital clinic to assess the performance of the Syphilis Health-Check test versus RPR and their reference treponemal tests - FTA and TPHA. Only gender and age were collected from these patients. A more comprehensive study was performed at three study sites to collect further patient history information in order to identify a broader range of STD related patients. The information and data collected from these sites is presented below.

   The Syphilis Health Check assay demonstrated 95.6% and 98.5% Percent Positive Agreement versus the non-treponemal test and treponemal tests, respectively, and 90.5% and 97.3% Percent Negative

Agreement, respectively.

Cumulative Comparison Results
The results obtained for the prospective and retrospective samples yields the following results compared to Non-treponemal RPR and treponemal tests.

Total Non-Treponemal Comparison - total combined sample results are presented from the 5 prospective sites and the frozen known and suspected positive samples.

		RPR - Non-Treponemal		
		Positive	Negative	Total
Syphilis Health Check	Positive	473	76	549
	Negative	22	721	743
	Total	495	797	1292

Percent Positive Agreement: 473/495 = 95.6% (95% C.I. = 93.4 - 97.2%)

Percent Negative Agreement: 721/797 = 90.5% (95% C.I. = 88.2 - 92.4%)

Percent Overall Agreement: 1194/1292 = 92.4% (95% C.I. = 90.8 - 93.8%)

Total Treponemal Comparison - total combined sample results are presented from the 5 sites and the frozen known and suspected positive samples

		Reference Treponemal tests		
		Positive	Negative	Total
Syphilis Health Check	Positive	531	20	551
	Negative	8	733	741
	Total	539	753	1292

Percent Positive Agreement: 531/539 = 98.5% (95% C.I. = 997.1 - 99.4%)

Percent Negative Agreement: 733/753 = 97.3% (95% C.I. = 95.9 - 98.4%)

Percent Overall Agreement: 1264/1292 = 97.8% (95% C.I. = 96.9 - 98.6%)

PROSPECTIVE STUDIES

University Clinic site

		RPR			FTA		
		pos	Neg	Total	pos	Neg	Total
Syphilis Health Check	Pos	32	1	33	27	6	33
	Neg	0	6	6	0	6	6
	Total	32	7	39	27	12	39

Percent Positive Agreement = 100.0% (95% C.I. = 89.1 - 100%) 100% (95% C.I. = 87.2 - 100%)
Percent Negative Agreement = 85.7% (95% C.I. = 42.1 - 99.6%) 50.0% (95% C.I. = 21.1 - 78.9%)
Percent Overall Agreement = 97.4% (95% C.I. = 86.5 - 99.9%) 84.6% (95% C.I. = 69.5 - 94.1%)

Hospital Clinic site

		RPR		
		pos	neg	Total
Syphilis Health Check	Pos	3	3	6
	Neg	0	44	44
	Total	3	47	50

TPHA		
pos	Neg	Total
6	0	
0	44	
6	44	50

Percent Positive Agreement = 100.0% (95% C.I. = 29.2 - 100%) 100.0% (95% C.I. = 54.1 - 100%)
Percent Negative Agreement = 93.6% (95% C.I. = 82.5 - 98.7%) 100.0% (95% C.I. = 92.0 - 100%)
Percent Overall Agreement = 94.0% (95% C.I. = 83.5 - 98.7%) 100.0% (95% C.I. = 92.9 - 100%)

Study Site 1

		RPR		
		pos	neg	Total
Syphilis Health Check	pos	13	15	28
	neg	2	370	372
	Total	15	385	400

TPPA		
pos	Neg	Total
21	8	29
6	365	371
27	373	400

Percent Positive Agreement = 86.7% (95% C.I.= 59.5 - 98.3) 77.8% (95% C.I.= 57.7 - 91.4)
Percent Negative Agreement = 96.1% (95% C.I.= 93.7 - 97.8) 97.9%(95% C.I.= 95.8 - 99.1)
Percent Overall Agreement = 95.8% (95% C.I.= 93.3 - 97.5) 96.5% (95% C.I.= 94.2 - 98.1)

It should be noted that two (2) of the false negative samples versus TPPA were only positive for TPPA but negative with the other two reference methods (RPR and FTA). Three samples were positive for TPPA and FTA, but negative for Syphilis Health Check and RPR.

Study Site 2

		RPR		
		pos	neg	Total
Syphilis Health Check	Pos	2	2	4
	Neg	0	85	85
	Total	2	87	89

TPPA		
pos	neg	Total
4	0	4
0	85	85
4	85	89

Percent Positive Agreement = 100.0% (95% C.I. = 15.8 - 100) 100.0% (95% C.I. = 39.8 - 100%)
Percent Negative Agreement = 97.7% (95%C.I. = 91.9 - 99.7) 100.0% (95% C.I. = 95.8 - 100%)
Percent Overall Agreement = 97.8% (95% C.I. = 92.1 - 100) 100.0% (95% C.I. = 95.9 - 100%)

Study Site 3

		RPR		
		pos	neg	Total
Syphilis Health Check	pos	6	4	10
	neg	0	195	195
	Total	6	199	205

EIA		
pos	neg	Total
9	2	11
1	193	194
10	195	205

P P A = 100.0% (95% C.I.= 54.1 - 100) 90.0% (95% C.I.= 55.5 - 99.7%)
P N A = 98.0% (95% C.I.= 94.9 - 99.4) 99.0% (95% C.I.= 96.3 - 99.9%)
P O A = 98.0% (95% C.I.= 95.1 - 99.5) 98.5% (95% C.I.= 95.8 - 99.7%)

RETROSPECTIVE STUDIES

Suspected and Known Positive Syphilis Samples

A series of 412 total samples were purchased from serum and blood center suppliers consisting of 149 banked RPR and treponemal reactive serum samples, 28 serum samples that were requested to be Primary or Secondary Patients, treated or untreated, but exhibiting a Syphilitic-type lesion or rash from a serum supplier, and 138 frozen serum and plasma samples from a blood center. The samples were found to be RPR and treponemal reactive and having mixed titers. Another series of 97 samples being highly suspected of having a syphilis infection were obtained from a serum supplier that were obtained from various laboratories around the U.S., and were submitted to the laboratories for testing. The samples were tested by RPR, TPPA, and MHA-TP as reference methods for comparison to Syphilis Health Check test.

The samples were further tested by an outside laboratory for TPPA titer and Syphilis Health Check results. Nineteen samples were found to be Negative for TPPA and Syphilis Health Check and Reactive RPR, four samples were negative by TPPA, but Positive by Syphilis Health Check and RPR, one sample was Syphilis Health Check negative and positive RPR and TPPA, and one sample was RPR neg but TPPA and Syphilis Health Check positive. The remaining two hundred eighty-nine samples remained Positive by all four methods. In the Suspected Positive patients two samples were negative with Syphilis Health Check, with one sample low reactive with RPR, and both samples Non-Reactive with TPHA. The results of the testing are shown below.

Known Positives

		RPR		
		pos	neg	Total
Syphilis Health Check	pos	293	1	294
	neg	20	1	21
	Total	313	2	315

TPPA		
pos	neg	Total
290	4	294
1	20	21
291	24	315

Percent Positive Agreement = 93.4% (95%C.I. = 89.8 - 96.0%) 99.6% (95%C.I.= 97.9 - 100.0%)
Percent Negative Agreement = 100.0% (95%C.I. = 100%) 85.7% (95%C.I.= 63.7 - 97.0%)
Percent Overall Agreement = 93.4% (95%C.I. = 89.8 - 96.0%) 98.6% (95%C.I.= 96.5 - 99.6%)

Suspected Positive

		RPR		
		pos	neg	Total
Syphilis Health Check	pos	62	25	87
	neg	0	10	10
	Total	62	35	97

TPHA		
pos	neg	Total
87	0	87
0	10	10
87	10	97

MHTP		
Pos	neg	Total
87	0	87
0	10	10
87	10	97

PPA = 100.0% (95% C.I. = 94.2 - 100%) 100.0% (95% C.I. = 95.8 - 100%) 100.0% (95% C.I. = 95.8 - 100%)
PNA = 28.6% (95% C.I. = 14.6 - 46.3%) 100.0% (95% C.I. = 69.2 - 100%) 100.0% (95% C.I. = 69.2 - 100%)
POA = 74.2% (95% C.I. = 64.3 - 82.6%) 100.0% (95% C.I. = 96.3 - 100%) 100.0% (95% C.I. = 96.3 - 100%)

Clinically Diagnosed

A panel of one hundred sixty-four (164) well-characterized clinically diagnosed serum samples from treated and untreated patients with primary, secondary, and latent syphilis infections were obtained from a clinic serving a

population of individuals with a variety of infectious diseases. The samples were tested with reference assay tests for RPR, TPPA, and FTA-ABS. The samples were then tested with Syphilis Health Check and the results are summarized below.

Known Clinical Status		RPR	TPPA	FTA-ABS	Syphilis Health Check	No.	% Agree-ment	95% C.I.
Untreated	Primary	React	React	React	React	23	100	85.2 - 100%
	Secondary	React	React	React	React	25	100	86.3 - 100%
	Latent	React	React	React	React	22	100	84.6 - 100%
		NR	React	React	React	3	100	29.2 - 100%
Treated	Primary	React	React	React	React	28	100	87.8 - 100%
	Secondary	React	React	React	React	26	100	86.8 - 100%
	Latent	React	React	React	React	18	100	81.5 - 100%
		NR	React	React	React	19	100	82.4 - 100%
					Total	164	100	97.8 - 100%

The results obtained from the clinical study appear to be acceptable.

b. *Clinical Specificity*

See section M.3.a

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected Values/Reference Range:

To assess the expected values (normal range) of the Syphilis Health Check test a series of ninety-eight samples were obtained from various hospital laboratories in different U.S. geographical locations. The samples came from a general "presumed" healthy normal population (ages 20 – 66 yrs) whose serum or plasma were collected by hospital laboratories for routine serology testing, not related to STD.

All of the samples were tested with RPR, TPPA and Syphilis Health Check tests. Two samples were found positive by the treponemal tests with both

samples non-reactive with RPR. These 2 samples were confirmed with MHA-TP.

The testing of a presumed normal population showed an overall agreement of 100% for the Syphilis Health Check test. Therefore from this study of ninety-eight presumed normal samples, two were confirmed positive resulting in a 2% positivity rate.

In a prospectively collected population of drug users visiting STD clinics, of 138 males and 13 females (ages 18 - 61 yrs), thirteen (8.6%) were found to be Syphilis Health Check test positive with eleven of those also reference method positive.

In a series of 69 pregnant women, ages 20 - 40 yrs, that were tested for routine screening, one sample (1.4%) was found to be Syphilis Health Check positive and confirmed by reference methods.

Eight hundred eighty (880) patients were prospectively collected in a population of individuals visiting STD and hospital clinics and POC sites complaining and/or exhibiting signs and symptoms of STD infections, ages 16 - 81 yrs, and having 53% to 47% male to female ratio. A range of 3% - 6% of the patients identified as suspected as having syphilis were found positive by Syphilis Health Check and yielded a Percent positive agreement to RPR of 98.3% and 95.7% to treponemal tests. Percent Negative Agreement to RPR and Treponemal test was 93.4% and 97.8%, respectively. Overall Agreement to RPR and Treponemal tests was 94.1% and 97.4%, respectively.

These results are consistent with published rates for prevalence of antibody in the adult population. Prevalence may vary depending on a variety of factors such as geography, age, socio-economic status, ethnic background, type of test employed, specimen collection and handling procedures, clinical and epidemiological history.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.