Becton, Dickinson and Company
Mary Ann Fiechtner
Regulatory Affairs Specialist
10865 Road to the Cure
Suite 200
San Diego, California 92121

March 20, 2018

Re: K180438
Trade/Device Name: BD Veritor System for Rapid Detection of Flu A + B CLIA Waived Kit
Regulation Number: 21 CFR 866.3328
Regulation Name: Influenza virus antigen detection test systems
Regulatory Class: Class II
Product Code: PSZ
Dated: February 15, 2018
Received: February 20, 2018

Dear Mary Ann Fiechtner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tamara V. Feldblyum -S for

Uwe Scherf, Ph.D.
Director
Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: *0613012020*
See *PRA Statement below*

51O(k) Number *(if known)*

K 180438

Device Name

BD Veritor System for Rapid Detection of Flu A + B – CLIA waived kit

Indications for Use *(Describe)*

The **BD Veritor** System for Rapid Detection of Flu A+B is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasal and nasopharyngeal swabs of symptomatic patients. The **BD Veritor** System for Rapid Detection of Flu A+B (also referred to as the **BD Veritor** System and **BD Veritor** System Flu A+B) is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. A negative test is presumptive and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Outside the U.S., a negative test is presumptive and it is recommended that these results be confirmed by viral culture or a molecular assay cleared for diagnostic use in the country of use. FDA has not cleared this device for use outside of the U.S. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. The test is not intended to detect influenza C antigens.

Performance characteristics for influenza A and B were established during January through March of 2011 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the *Morbidity and Mortality Weekly Report* from the CDC entitled "Update: Influenza Activity—United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine." Performance characteristics may vary against other emerging influenza viruses.

If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to the state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda. hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(K) SUMMARY

DATE PREPARED: March 16, 2018

SUBMITTED BY:
BECTON, DICKINSON AND COMPANY
10865 Road to the Cure, Suite 200
San Diego, CA 92121
Tel: (858) 795-7857
Fax: (858) 812-8505

CONTACT NAME:
Mary Ann Fiechtner, RAC
Regulatory Affairs Specialist

DEVICE TRADE NAME: BD Veritor™ System for Rapid Detection of Flu A + B CLIA-Waived Kit

DEVICE COMMON NAME: Influenza Virus Antigen Detection Test System

DEVICE CLASSIFICATION: 21 CFR 866.3328

CLASSIFICATION: CLASS 2

PANEL: Microbiology

PREDICATE DEVICES : BD Veritor™ System for Rapid Detection of Flu A+B CLIA waived kit (k112277, k132259, k132692, k151291, k160161)

INTENDED USE :
The BD Veritor System for Rapid Detection of Flu A+B CLIA waived assay is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral nucleoprotein antigens from nasal and nasopharyngeal swabs of symptomatic patients.

The BD Veritor System for Rapid Detection of Flu A+B (also referred to as the BD Veritor System and BD Veritor System Flu A+B) is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single device. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. A negative test is presumptive and it is recommended that these results be confirmed by viral culture or an FDA-cleared influenza A and B molecular assay. Outside the U.S., a negative test is presumptive and it is recommended that these results be confirmed by viral culture or a molecular assay cleared for diagnostic use in the country of use. FDA has not cleared this device for use outside of the U.S. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other patient management decisions. The test is not intended to detect influenza C antigens.

Performance characteristics for influenza A and B were established during January through March of 2011 when influenza viruses A/2009 H1N1, A/H3N2, B/Victoria

lineage, and B/Yamagata lineage were the predominant influenza viruses in circulation according to the Morbidity and Mortality Weekly Report from the CDC entitled “Update: Influenza Activity—United States, 2010-2011 Season, and Composition of the 2011-2012 Influenza Vaccine.” Performance characteristics may vary against other emerging influenza viruses.

If infection with a novel influenza virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent influenza viruses and sent to the state or local health department for testing. Virus culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

DEVICE DESCRIPTION :

A. Summary

The BD Veritor System for Rapid Detection of Flu A+B is a rapid chromatographic immunoassay for the direct and qualitative detection of influenza A and B viral antigens from nasopharyngeal and nasal swabs of symptomatic patients. The test is to be used as an aid in the diagnosis of influenza A and B viral infections. It is a differentiated test, such that influenza A viral antigens can be distinguished from influenza B viral antigens from a single processed sample using a single test device. Negative test results do not preclude influenza viral infection and should not be used as the sole basis for treatment or other management decisions. All negative test results should be confirmed by another methodology, such as a nucleic acid based method. All BD Veritor System Flu A+B test devices are interpreted by a BD Veritor System Instrument, either a BD Veritor Reader or BD Veritor Plus Analyzer.

B. Principle of the Test

The BD Veritor Flu A+B test is an immuno-chromatographic assay for detection of influenza A and B viral antigens in samples processed from respiratory specimens. The viral antigens detected by the BD Flu A+B test are nucleoprotein, not hemagglutinin (HA) or neuraminidase (NA) proteins. Flu viruses are prone to minor point mutations (i.e., antigenic drift) in either one or both of the surface proteins (i.e., HA or NA). The BD Flu A+B test is not affected by antigenic drift or shift because it detects the highly conserved nucleoprotein of the influenza viruses[1,2]. To perform the test, the patient specimen swab is treated in a supplied reaction tube prefilled with a lysing agent that serves to expose the target viral antigens, and then expressed through a filter tip into the sample well on a BD Veritor Flu A+B test device. Any influenza A or influenza B viral antigens present in the specimen bind to anti-influenza antibodies conjugated to colloidal gold micro-particles on the Veritor Flu A+B test strip. The antigen-conjugate complex then migrates across the test strip to the capture zone and reacts with either Anti-Flu A or Anti-Flu B antibodies that are immobilized on the two test lines on the membrane.

---

[1] Shu, L.L., Bean, W.J., and Webster, R.G. 1993. Analysis of the evolution and variation of the human influenza A virus nucleoprotein gene from 1933 to 1990. J. Virol. *67*:2723-2729.

[2] Kendal, A.P., and Dowdle, W.R. 1986. Influenza Virus p. 515. Manual of Clinical Laboratory Immunology, 3rd edition, *In* Lenette et. Al. (ed.). American Society for Microbiology, Washington, D.C.

The BD Flu A+B test device shown in Figure 1 is designed with five spatially-distinct zones including positive and negative control line positions, separate test line positions for the target analytes, and a background zone. The test lines for the target analytes are labeled on the test device as 'A' for flu A position, and 'B' for flu B position. The onboard positive control ensures the sample has flowed correctly and is indicated on the test device as 'C'. Two of the five distinct zones on the test device are not labeled. These two zones are an onboard negative control line and an assay background zone. The active negative control feature in each test identifies and compensates for specimen-related, nonspecific signal generation. The remaining zone is used to measure the assay background.

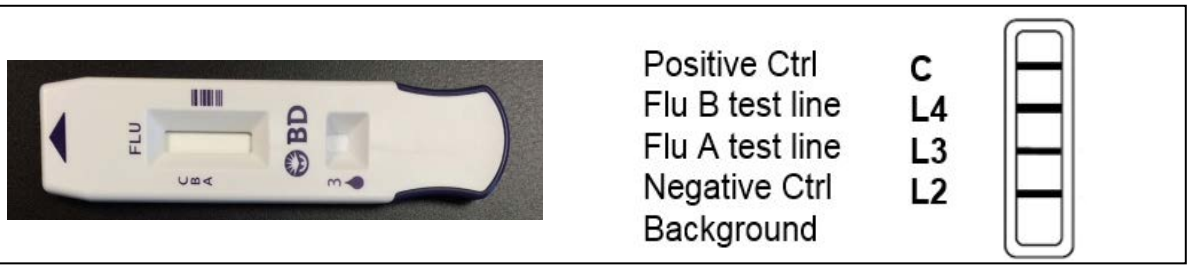


Figure 1. BD Veritor Flu A + B Assay Device

C. System Components

The Veritor System is made up of assay kits with analyte specific reagents and an opto-electronic interpretation instrument.

D. Flu A + B CLIA waived assay kit contents

The components included in the BD Veritor System for Rapid Detection of Flu A+B CLIA waived test kit (BD product #256045) are detailed in Table 1.

Table 1: Contents of the Veritor System for Rapid Detection of Flu A + B CLIA waived kit

Veritor™ System Flu A+B Test Devices	30 Test Devices	Foil pouched device containing one reactive strip. Each strip has two test lines of antibodies specific to either influenza A or influenza B viral antigen, and positive and negative control lines.
RV Reagent D	30 tubes with 400 µL reagent	Detergent with less than 0.1% sodium azide (preservative)
Flexible minitip flocked swab	30 each	Swab for nasopharyngeal or nasal collection
Control A+/B-	1 each	Flu A positive and flu B negative control swab, influenza A antigen (inactive recombinant nucleoprotein) with less than 0.1% sodium azide
Control B+/A-	1 each	Flu B positive and flu A negative control swab, influenza B antigen (inactive recombinant nucleoprotein) with less than 0.1% sodium azide

E. Veritor™ System Interpretation Instruments

The BD Veritor System instruments use a reflectance-based measurement method and apply assay specific algorithms to determine the presence or absence of the target analyte. In the case of the Flu A + B test, the BD Veritor System instruments subtract

nonspecific signal at the negative control line from the signal present at both the Flu A and Flu B test lines. If the resultant line signal is above a pre-selected assay cutoff, the specimen scores as positive. If the resultant line signal is below the cutoff, the specimen scores as negative. Use of the active negative control feature allows the BD Veritor System instruments to correctly interpret test results that cannot be scored visually because the human eye is unable to accurately perform the subtraction of the nonspecific signal. The measurement of the assay background zone is an important factor during test interpretation as the reflectance is compared to that of the control and test zones. A background area that is white to light pink indicates the device has performed correctly. Sample preparation is the same for use with both instruments, and both can utilize the same kit components. Neither instrument requires calibration.

The Veritor Reader and the Veritor Plus Analyzer use the functional components and decision algorithm in the firmware. The BD Veritor Plus Analyzer has the flexibility of an optional bar code scanning module and cellular connectivity designed to facilitate record keeping as well as the addition of a "Walk Away" work flow mode. Depending on the configuration chosen by the operator, the Veritor Plus Analyzer communicates status and results to the operator via a liquid crystal display (LCD) on the instrument, a connected printer, or through a secure connection to the facility's information system.

The following components are included with the BD Veritor™ Instruments (purchased separately from Veritor Assays).

Table 2: Veritor System Instrument components

BD Veritor™ Reader		
BD Veritor™ System Reader	1 each	Portable, rechargeable instrument for interpretation of BD Veritor™ System test devices
AA Alkaline Batteries	2 each	Reader arrives ready to use with batteries installed.
Instructions for Use	1 each	Printed instructions for use
BD Veritor™ Verification Cartridge	1 each	Used to verify the proper functionality of the Reader.
BD Veritor™ Plus Analyzer		
BD Veritor™ Plus System Analyzer	1 each	Portable, rechargeable instrument for interpretation of BD Veritor™ System test devices
Instructions for Use	1 each	Printed instructions for use
USB Port Unlock Label	1 each	Adhesive label used to unlock the USB port
Compact AC power Adapter with blades for USA, Japan, UK and EU	1 each	Used to charge the internal rechargeable battery power source.
BD Veritor™ Verification Cartridge	1 each	Used to verify the proper functionality of the Analyzer.

Table 3: Optional Veritor System accessory module compnents

BD Veritor™ Plus System InfoScan Module		
Barcode scanning module	1 each	Allows users to capture and record or display user ID, patient ID and/or kit lot ID numbers with an associated assay result
Quick Installation guide	1 each	Pictogram illustrating simple, slide in installation
USB Cable (USB-A to micro-B)	1 each	Allows download of assay results to a connected PC from the secure internal drive.
BD Veritor™ Plus System InfoSync Module		
Cellular enabled barcode scanning module	1 each	Allows users to capture and record user ID, patient ID and/or kit lot ID numbers, and transmit them to a cloud connected LIS system with associated assay results.
Quick Installation guide	1 each	Pictogram illustrating simple, slide in installation

DEVICE COMPARISON:

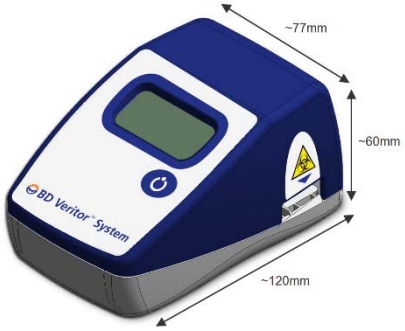
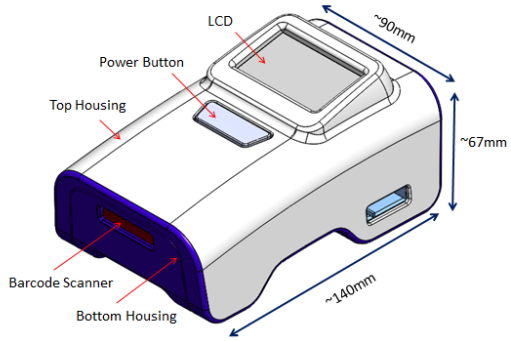
The device labeling has been changed to reflect the addition of a new data table and explanation in the Clinical Performance section. This appears as Table 1 in the Package Insert as shown below.

Table 1: Summary of Performance Data of the BD Veritor System for Rapid Detection of Flu A + B Compared to PCR for All Swabs - All Sites.

Note: The data in this table summarizes the performance of the Veritor Flu A + B assay test system across all age groups, clinical testing sites and sample types. The 95% Confidence intervals are calculated using an analysis that accounts for sources of heterogeneity.

	Reference PCR					Reference PCR		
POC: BD Flu A	P	N	Total		POC: BD Flu B	P	N	Total
P	189	13	202		P	139	10	149
N	37	497	534		N	32	555	587
Total	226	510	736		Total	171	565	736
Reference Method: PCR PPA: 83.6% (76.1%, 89.1%) NPA: 97.5% (95.7%, 98.5%)					Reference Method: PCR PPA: 81.3% (71.1%, 88.5%) NPA: 98.2% (95.7%, 99.3%)			
Wald 95% Confidence intervals corrected for over-dispersion, where needed, due to potential variability between sites.								

Table 5: Comparison of Veritor System Reader and Veritor Plus Analyzer

Product Feature	Veritor System Reader	Veritor Plus Analyzer
GENERAL:		
Appearance and dimensions		
Intended use	For use with BD Veritor System test devices	Same
Firmware functional verification	Verification cartridge supplied with each Reader	Same
Assay type determination	Internal camera reads barcode on test device	Same
Assay test device compatibility	Original	Same
Lifetime	3000 tests 24 months from first use 34 months from date of manufacture	3500 tests 24 months from first use 34 months from date of manufacture
Assay workflow options	Original or “Analyze Now”: Assay device is prepared with processed patient sample, user manually times the assay development and inserts assay device when development time is complete.	• Analyze Now: unchanged • Walk-Away: Assay device is prepared with processed patient sample, inserted into the Analyzer immediately. Assay development is automatically timed by the instrument and result is displayed when development time is complete.
Qualitative or Quantitative Result	Qualitative	Qualitative, unchanged
Optional modular barcode scanner	Not Present	Captures and records Operator ID, Specimen ID, and/or test device lot information. Can be used to configure display languages.
Cellular modem available with InfoSync module	Not Present	Using HTTPS secure link, endpoint authentication, receipt confirmation. Automated connection to LIS/EMR.
Removable module or cover plate	Not Present	Analyzers have either a cover plate or are equipped with optional scanning module.

Printer	Not printer compatible	Compatible with external dedicated printer via USB.
ELECTRICAL:		
Batteries	User replaceable alkaline AA batteries	Li-ion rechargeable battery
AC power adapter	N/A	To charge the Li-ion battery and/or operate the analyzer from facility power.
Graphical display	40 mm x 19 mm	56 mm x 33 mm
Flash Memory	4 MB	8 MB
FIRMWARE:		
Assay positivity algorithm	Original	Same
Assay cutoff thresholds	Original	Same
Test menu	Original	Same
Cybersecurity controls	Not Present	To meet requirements for data privacy and anti-hacking protection.
USB OTG port	Not Present	To connect to printer or to a computer to display or print results. Input firmware or menu updates from flash drive.
Display languages	English or Japanese only	Six user selectable languages; English, French, Italian, German, Spanish, Swedish. (optional scanning module required for language configuration). Japanese model sold separately.

SUBSTANTIAL EQUIVALENCE:

The modified BD Veritor™ System Flu A+ B CLIA waived kit is substantially equivalent to the current legally marketed, BD Veritor™ System Flu A+B CLIA waived kit. Additions made to the labeling to add the performance data table and to allow interpretation with the Veritor Plus Analyzer have changed neither the intended use of the device nor the fundamental scientific technology.

RISK ASSESSMENT SUMMARY:

The BD Diagnostic Systems Risk Assessment process is based on the BD Risk Management procedure, which meets the requirement for risk management as set forth in ISO 14971:2007 and EN ISO 14971:2012. Using this procedure, the following are estimated:

- the Hazard,
- the Adverse Effect (Harm to Patient),
- the Potential Causes of the Hazard,
- The probability of Hazard Severity and
- The probability of Occurrence

Based on a resulting calculated risk index, risk control measures are identified, required verification and validation activities are determined, and verification of the effectiveness of risk control measures is determined.

RESULTS OF THE RISK ANALYSIS:

1. Addition of the inclusion of the additional performance table in the Clinical Performance section of the BD Veritor™ System Flu A+ B CLIA-Waived assay product insert does not create any new product risks, or issues of safety and effectiveness.

Additions to labeling are as follows:

Change	**Potential Impact of Change**
Addition of performance data re-analyses	Additional information provided to users regarding performance of the device.

2. The risk assessment identified the need to confirm the Veritor Plus System's ability to produce assay results equivalent to those obtained with the Veritor Reader in either Analyze Now or Walk Away work flow mode. The identified studies were performed according to appropriate design control procedures to assess the addition of the Veritor Plus Analyzer in either mode as an interpretation instrument for the Veritor System Flu A + B CLIA-Waived assay product. The results of testing did not identify new issues of safety and effectiveness.

3. The risk assessment identified the need to confirm that the addition of the bar code scanning functions of InfoScan and InfoSync modules, and any associated screen displays, alerts and error messages had no effect on safety or effectiveness when

the Veritor Plus Analyzer was used with the Veritor CLIA-waived Flu A + B Assay. Software verification activities were performed and all testing criteria were met to confirm that changes and addtions made to firmware to add new functionality had no impact on the abiltiy of the instrument to give a correct assay result.

4. Cybersecurity risks and vulnerabilities associated with the use of the InfoSync module were assessed and BD procedures and controls were verified as acceptable to protect user and patient data.

5. The risk assessment also identified the need to confirm that the Veritor Plus Analyzer was simple and easy to use in the CLIA waived environment.

SUMMARY OF PERFORMANCE STUDIES:

At the BD Diagnostics Systems research and development center in San Diego, CA, staff performed studies on both analytical and clinical samples to confirm that the performance of the Veritor Plus Analyzer is equivalent to the Veritor Reader when used in both Read Now and Walk-Away modes.

These studies included:

- Reproducibility studies
    - Samples with true zero values (no analyte)
    - High negative and low positive samples (near cut-off samples)

The data collected using analytical samples demonstrated that the percentage positivity for Veritor Readers and Veritor Plus Analyzers are equivalent.

The R&D staff also performed assessments of the following clinical samples:

- 102 Flu A-/B- samples
- 52 Flu A+ samples
- 52 Flu B+ samples

The data collected with clinical samples also indicate that assay results obtained using Veritor Readers and Veritor Plus Analyzers are either identical or statistically equivalent. Results included less than 2% either False Positive or False Negative results.