



**SIMPLIFIED AND PRACTICAL GUIDE TO CLIA REQUIREMENTS FOR
VERIFICATION OF THE FDA CLEARED BECTON DICKINSON
BD PROBE TEC HSV Q^x AMPLIFIED DNA ASSAYS**

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INTRODUCTION

This document is provided by Becton Dickinson Diagnostics to Clinical Laboratory Improvement Act (CLIA) high-complexity clinical laboratories to guide them through a simple but required process to validate the FDA cleared BD ProbeTec HSV Q^x Amplified DNA Assays.

This guide will not cover in-house laboratory developed tests using ASRs or *modified* FDA cleared assay FDA requirements, which are different. Most laboratories prefer to use FDA cleared assays and as you will see that verification process is much simpler and more straightforward than what is required for laboratory developed in-house (home brew) assays or those assays modified from a manufacturer's original FDA cleared product.

SECTION 1: CLIA REQUIREMENTS FOR NEW ASSAY VERIFICATION

CLIA regulations require that assays such as the BD ProbeTec HSV Q^x Amplified DNA Assays undergo a process to insure performance specifications prior to the assay being used to report patient results. This one-time activity is called *verification* and basically is a process to insure that a “new” assay the laboratory wishes to employ performs in the hands of the laboratory in the manner in which it was intended by the manufacturer.

According to the CLIA standard for either moderate or high complexity assays, this is required whenever a laboratory wishes to “replace a test system or instrument (with the same model or a different model), adds a new test, or changes the manufacturer of a test system.”

Detailed requirements are found on the CDC web site containing CLIA Subpart K Quality Systems for Nonwaived Testing http://wwwn.cdc.gov/clia/regs/subpart_k.aspx CLIA guidance that relates to the FDA cleared BD ProbeTec HSV Q^x Amplified DNA Assays can be found at Sec. 493.1253 (b) (1) (i) – (ii)

(b)(1) Verification of performance specifications. Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results:

(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics:

(A) Accuracy.

(B) Precision.

(C) Reportable range of test results for the test system.

(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

Useful CLIA interpretative guidelines for Sec. 493.1253 (b) (1) (i) – (ii) are located at <http://www.cms.gov/CLIA/downloads/apcsubk1.pdf>

Interpretive Guidelines for Sec. 493.1253(b)(1)(i) state that with some preplanning a laboratory may “*simultaneously verify multiple performance specifications by choosing appropriate samples; e.g., repeatedly test (precision) samples with known (accuracy) high and low values (reportable range).*” The CLIA interpretative guide goes on to state that testing should be performed among all operators on different days. This action constitutes the method of testing that meets CLIA guidelines for precision.

SECTION 2: SIMPLE VERIFICATION PLAN AND TEMPLATE

To recap, the completed verification study must, at its simplest, insure that the new assay performs in a manner comparable to the specifications established by the manufacturer in regards to accuracy, precision and reportable range and insure that the manufacturer's stated normal values are appropriate for the population tested by the laboratory.

Further, the laboratory must insure that the verification study incorporates all of the parameters necessary to meet the CLIA requirements and must be robust enough to satisfy CLIA inspectors.

From an economic point of view and to be able to rapidly review the newest technology, laboratory management should strive to accomplish all of the necessary CLIA verification requirements in one simple verification study designed to capture all of the components at one time.

The ideal goal is to acquire samples of known high and low positive reactivity and negative reactivity that are typical of the laboratory's patient population; and then test the samples in a manner that would include several parallel runs, in duplicate, performed over several days and by all licensed professional laboratorians. Fortunately, this goal is not that difficult to achieve when verifying the BD ProbeTec HSV Q^x Amplified DNA Assays,

The following is a proposed verification plan for both an in-house comparison to an existing assay or for a laboratory that will use previously characterized samples.

Correlation Study for Accuracy (Agreement): Accuracy shall be determined by method comparison of testing specimens with known positive and negative values for the test being evaluated (BD ProbeTec HSV Q^x Amplified DNA Assays) and the existing routinely used assay or previously characterized samples. If parallel testing is taking place, it shall be performed at the same time with split samples run in both the existing assay and the new assay.

Positive and negative results of the two assays when compared or when the BD ProbeTec HSV Q^x Amplified DNA Assays are compared to previously characterized samples obtained elsewhere will be put into the following Table.

BD ProbeTec HSV (1or 2)	Comparative Method		
	Positive	Negative	Total
Positive	a	b	a + b
Negative	c	d	c + d
Total	a + c	b + d	n

Percent Accuracy (Agreement) Calculation: Statistical calculation of accuracy will be performed using the following formula. $(a + d)/n \times 100 = X$

Acceptance Criteria: ≥ 90 % accuracy for detecting HSV 1 and 2 DNA each, when compared to the reference method. When an assay has lower sensitivity than the new assay to be verified one should expect that discrepant resolution will be necessary. This is because some specimens may be identified as false positive results in a new more sensitive assay. Said another way, the existing technology could miss true positives since the assay may have lower sensitivity. If the accuracy calculation of the BD ProbeTec HSV Q^x Amplified DNA Assays is less than 90%, discrepant resolution will be necessary. See **SECTION 4: DISCORDANT RESOLUTION**

Precision (Reproducibility): Precision shall be determined by testing specimens with known high and low positive and negative values for the test being evaluated (BD ProbeTec HSV Q^x Amplified DNA Assays) in duplicate over a period of three or more runs and two or more days with at least one run performed by each professional laboratorian.

Note: Low positive samples can be prepared by dilution of high positive specimens in the proper buffer to obtain the necessary specimens since one is simply trying to establish comparison between the existing (acceptable) assay and that being evaluated (BD ProbeTec HSV Q^x Amplified DNA Assays).

To determine precision, the results from the runs will be recorded below.

BD ProbeTec HSV (1or 2)	Comparative Method <i>TRUE</i> Result		
	Positive	Negative	Total
Positive	True Pos (a)	False Pos (b)	a + b
Negative	False Neg (c)	False Neg (d)	c + d
Total	a + c	b + d	n

Precision Calculation: Statistical calculation of precision will be performed using the following formula. $a \div (a + b) \times 100 = X$

Acceptance Criteria: ≥ 95 % precision must be obtained for detecting HSV 1 and 2 DNA when compared to the reference method.

Reportable Range Of Test Results: During the accuracy study specimens with known high and low positive reactivity with some of the known positive specimens at the upper and lower limits of the manufacturer's reportable range and negative values for the tests being evaluated (BD ProbeTec HSV Q^x Amplified DNA Assays) were tested. Specimens were run in duplicate over a period of three or more runs and two or more days with at least one run performed by each professional laboratorian. The results of those assays will be used to validate the reportable range.

A definition of what constitutes a "Positive," a "Negative," an unsatisfactory and/or any other statement for reportable ranges for FDA cleared assays must be stated by the manufacturer and in the standard operating protocols for the laboratory using the assay.

In the case of the BD ProbeTec HSV Q^x Amplified DNA Assays this is found in the manufacturer's package insert seen in the following table for both HSV1 and HSV2.

HSV Q ^x Assays Interpretation of Results for the HSV1 and HSV2 Q ^x Assays			
HSV Q ^x MaxRFU	Report	Interpretation	Result
≥125	HSV DNA detected by SDA	Positive for HSV DNA	Positive
<125	HSV DNA not detected by SDA	Negative for HSV DNA	Negative
<125	Extraction control failure. Repeat test from initial specimen tube or obtain another specimen for testing.	Non-reportable result	Extraction Control Failure
Any value	Extraction Transfer Failure. Repeat test from initial specimen tube or obtain another specimen for testing.	Non-reportable result	Extraction Transfer Failure
Any value	Liquid Level Failure. Repeat test from initial specimen tube or obtain another specimen for testing.	Non-reportable result	Liquid Level Failure
Any value	Error. Repeat test from initial specimen tube or obtain another specimen for testing.	Non-reportable result	Error

Acceptance Criteria: ≥90 % accuracy for detecting HSV 1 and 2 DNA when compared to the reference method when some of the known positive specimens are at the upper and lower limits of the manufacturer's reportable range.

Reference Range: This means the “normal range” for the population being served or tested and will be verified by the results of the accuracy study above. Numerous peer-reviewed articles and the BD ProbeTec HSV Q^x Amplified DNA Assays package insert have established that “normal” for most healthy patient populations would be a result of “HSV DNA not detected by SDA” or negative. This information must be stated by the manufacturer for FDA cleared assays and must be in the standard operating protocols for the laboratory using the assay.

SECTION 3: VERIFICATION STUDY DESIGN

Potential verification study protocols that could be used to verify the BD ProbeTec HSV Q^x Amplified DNA Assays follow in this section. They are briefly described here.

I. Verification study: Laboratories that *have* archived characterized HSV remnant specimens collected in Universal Transport Medium (UTM) and Laboratories that *do not* have an alternate HSV procedure in place

The easiest pathway to meet CLIA requirements for verification would be to use clinical samples that have been previously analyzed by the BD ProbeTec HSV Q^x Amplified DNA Assays or other methods (e.g. culture, PCR) or to use “spiked” samples that have the agent (HSV 1 & HSV 2) mixed with the appropriate buffer or diluent at various concentrations to obtain high and low positive sample types that have also been characterized that have also been characterized by the same or another assay.

Some laboratorians advocate calculation of sensitivity, specificity, negative and positive predictive values. However, this is not necessary for unmodified FDA-cleared assays, such as the BD ProbeTec HSV Q^x Amplified DNA Assays. All that is required is acceptable accuracy (agreement) of the assays, precision (reproducibility) and reportable range. As long as the manufacturer’s package insert contains the reference range for the assay, as is the case for the BD ProbeTec HSV Q^x Amplified DNA Assays, the only studies that are left to perform are the accuracy and precision studies and the reportable range determination in order to meet CLIA requirements. This makes the change to newer or better technology that is unmodified from the FDA cleared assay rather simple.

A. Number of specimens to be tested:

The simple rule of thumb is to have at least 20 positive specimens to be compared. <http://www.cms.gov/clia/downloads/6064bk.pdf> Given that on average in the United States, the prevalence of HSV 1 or 2 in populations being tested for presence of either HSV 1 or 2 will be well over 5% and upwards of 20% for HSV 2. Somewhere between 100 and 300 specimens should yield 20 positive specimens for each analyte and be sufficient to evaluate the BD ProbeTec HSV Q^x Amplified DNA Assays. See **Section 5:** Statistical Analysis and Templates to determine your laboratory’s population statistics

B. Correlation study for accuracy (agreement):

1. Obtain your own previously characterized archived samples stored properly in UTM or spiked samples obtained from a laboratory or quality control reagents from a vendor that has already evaluated the samples using the BD ProbeTec HSV Q^x Amplified DNA Assays.
2. Store samples properly until analysis.
3. Dilute at least two samples to give a range that is at the upper and lower limits of the manufacturer’s reportable positive range in the package insert.
4. Process previously tested samples per the BD ProbeTec HSV Q^x Amplified DNA Assays package insert.
5. Compare and analyze the data obtained. See **Section 4:** Statistical Analysis
6. Verification Proposal –Review and approval See **Section 5:** Verification Report

C. Precision study: (This step can be potentially accomplished in B. above)

1. 20 samples with known high and low positive and negative values for the assay being evaluated (BD ProbeTec HSV Q^x Amplified DNA Assays) and the existing assay shall be tested in duplicate. Two of the known positive specimens used in the precision study will be at the upper and lower detection limits of the BD ProbeTec HSV Q^x Amplified DNA Assays reportable range found in the package insert. Obtain your own previously characterized archived samples stored properly in UTM or spiked samples obtained from a laboratory or quality control reagents from a vendor that has already evaluated the samples using the BD ProbeTec HSV Q^x Amplified DNA Assays.
2. Separate runs using the same specimens will be performed over a period of at least three runs.
3. Runs will span a time period of at least two separate days.
4. At least one run will be performed by each professional laboratorian who will run the BD ProbeTec HSV Q^x Amplified DNA Assays.
5. Compare and analyze the data obtained. See **Section 4:** Statistical Analysis
6. Verification Proposal –Review and approval See **Section 5:** Verification Report

D. Reference range: The range shall be verified by testing specimens of known reactivity near the manufacturer’s stated reportable range and at the normal range during the accuracy study (at I B. , above). Two of the known positive specimens used in the accuracy and precision study were at the upper and lower limits of the manufacturer’s reportable range found in the package insert.

HSV Q ^x Assays Interpretation of Results for the HSV1 and HSV2 Q ^x Assays			
HSV Q ^x MaxRFU	Report	Interpretation	Result
≥125	HSV DNA detected by SDA	Positive for HSV DNA	Positive
<125	HSV DNA not detected by SDA	Negative for HSV DNA	Negative

II. Verification Study: Method comparison for laboratories with alternate NAAT or non-NAAT HSV assays using simultaneous prospectively collected specimens from their own patients

Laboratories that have an established HSV assays in place and in routine use in the laboratory might follow this design. A basic comparison of the laboratory’s existing established procedure and the new BD ProbeTec HSV Q^x Amplified DNA Assays would be in order. Since the comparison of specimen collection devices and the assay is necessary, the simplest way to accomplish this would be a side by side or parallel comparison of specimens collected from the same patient looking for concordance between the two assays.

Further, this approach may require the approval by an Institutional Review Board (IRB) prior to beginning the study thus complicating what should be a very simple process. Some laboratories may have access to an IRB as an established part of the organization, in which case, they would work through their IRB to obtain the necessary approval. Once the appropriate guidance is obtained from the IRB, the study design can take place.

A. Number of specimens to be tested: See I A. above

B. Correlation study for accuracy (agreement):

1. Obtain 2 specimens from each patient, one for each of the 2 assays to be compared.
2. For the BD ProbeTec HSV Q^x Amplified DNA Assays use the BD ProbeTec Q^x Collection Kit for Endocervical or lesion Specimens collected according to the package insert in its appropriate BD Q^x Swab Diluent Tube.
3. Collect the other specimen according to the established procedure for the comparator assay in its appropriate transport medium as prescribed by the manufacturer.
4. Randomize the order in which the specimens are taken.
5. Compare and analyze the data obtained. See **Section 4:** Statistical Analysis
6. Verification Proposal – Review and approval. See **Section 5:** Verification Report

Note: two different specimen collection devices can be used in the BD ProbeTec HSV Q^x Amplified DNA Assays. Therefore if these different types of specimens are, used by laboratory submitters, they need to be included in the verification study. If more than one collection device will be accepted by the testing laboratory then test at least 10 positives and 10 negatives of each collection device.

1. The BD Universal Viral Transport (UVT) - 3 mL fill volume and regular sized polyester fiber tip swab with a plastic shaft (Cat. Nos. 220220, 220221, 220239)
2. The identical Copan Universal Transport Medium (UTM-RT) System (Cat. No. 302C, 302C.LC, 330C, 340C and 321C)
3. The BD ProbeTec Q^x Collection Kit for Endocervical or Lesion Specimens

C. Precision Study: See I C. above

D. Reference range: See I D. above

SECTION 4: DISCORDANT RESOLUTION

It is well known that when ever an older technology (e. g. culture or EIA) that may have lower analytical sensitivity is compared to molecular assays, there will be discordant results. This is usually due to the much higher sensitivity of the molecular assays, which results in the molecular assay identifying more positive results. To some extent one could say that a direct comparison puts molecular assays at a disadvantage when compared to technology that is known to have a lower sensitivity. To remediate this concern discordant resolution may be necessary to compare results and to verify the “true” result expected from the sample tested. Repeat testing or sequencing may be very useful in resolving this issue.

Discordant test results occur when initial test results from the BD ProbeTec HSV Q^x Amplified DNA Assays do not agree with the result obtained from a comparator assay. These specimens can be subjected to further analysis to ascertain their true result and then the statistics can be recalculated using resolved data.

Procedure for Discordant Resolution:

A. Repeat Testing:

1. Re-test only discordant samples using the BD ProbeTec HSV Q^x Amplified DNA Assays.
2. If the results of the initial comparator and the *repeat* BD ProbeTec HSV Q^x Amplified DNA Assays result is still discordant, the matching remnant specimen will be re-tested using another assay or at a reference laboratory.
3. *Concordant* results of the comparator assay and the repeat BD ProbeTec HSV Q^x Amplified DNA Assays are considered final results and no further testing is required.
4. Recalculate statistics.

B. Third Party Referee Method:

1. Send only discordant specimens to the reference laboratory for alternate NAAT assay.
2. Consider the result obtained by the reference laboratory as final results.
3. Recalculate statistics

SECTION 5: STATISTICAL ANALYSIS AND TEMPLATES

Calculation of Number of Specimens to Be Tested

If the laboratory's positivity rate is 10% then 200 specimens will need to be tested to reach the goal of sufficient positive results (20). We can express this in a simple formula where X is the number of specimens needed and Y is the laboratory's percent positive for the test (HSV 1-2), then; $X = 20 \div Y$. For example, if a laboratory has a percent positive of HSV1 of 7.5%, then the approximate number of specimens the laboratory needs to test would be $20 \div .075 = 267$.

Accuracy (Agreement)

The rule of thumb is to have a total or overall 90% or better agreement of the new assay with the old assay. Add the results obtained to a table similar to the one below.

BD ProbeTec HSV	Comparative Method		
	Positive	Negative	Total
Positive	a	b	a + b
Negative	c	d	c + d
Total	a + c	b + d	n

Percent Agreement Calculations:

Minimally, CLIA requires an overall 90% percent agreement between the two assays. The formula $(a + d) \div n \times 100 = X$ provides this information.

While not specifically required, one can choose to calculate both the Percent Positive Agreement (PPA) and the Negative Percent Agreement (NPA) using data obtained in the study.

The PPA of the **BD ProbeTec HSV** is expressed as $a \div (a + c) \times 100$; while the NPA would be expressed as $d \div (b + d) \times 100$.

A 95% confidence interval for PPA and NPA *can* be estimated using readily available statistical software or manually, but is not specifically required.

Precision (reproducibility):

Precision can be defined as the proportion (percentage) of true positives (those determined by the "gold standard) or existing in-house assay when compared to all positive results whether they are true or false positive results.

Add the results obtained from the precision study to a table similar to the one below.

BD ProbeTec HSV	Comparative Method <i>TRUE</i> Result		
	Positive	Negative	Total
Positive	True Pos (a)	False Pos (b)	a + b
Negative	False Neg (c)	False Neg (d)	c + d
Total	a + c	b + d	n

Precision (Reproducibility) Calculations:

The precision obtained in evaluating the BD ProbeTec HSV Q^x Amplified DNA Assays can be expressed as a percentage using this formula and the data from the table above

$$a \div (a + b) \times 100 = X$$

SECTION 6: VERIFICATION REPORT TEMPLATE

Laboratory Name/Section

Accuracy (BD ProbeTec HSV 1) by method comparison

BD ProbeTec HSV 1	Comparative Method		
	Positive	Negative	Total
Positive			
Negative			
Total			

Percent Accuracy Calculation Result (list): _____ %

Acceptance criteria: ≥90 % overall agreement for detecting HSV 1 DNA when compared to the reference method. Yes No

If Yes, Conclusion:

The BD ProbeTec HSV Q^x Amplified DNA Assay was able to detect the presence or absence of HSV 1 DNA equally as well as the comparator assay. The BD ProbeTec HSV Q^x Amplified HSV 1 DNA Assay meets the verification standard.

If No, Conclusion:

The BD ProbeTec HSV Q^x Amplified DNA Assay was not able to detect the presence or absence of HSV 1 DNA equally as well as the comparator assay. The BD ProbeTec HSV Q^x Amplified HSV 1 DNA Assay does not meet the verification standard. Review protocol, procedures, mitigate and repeat, if necessary.

Accuracy (BD ProbeTec HSV 2) by method comparison

BD ProbeTec HSV 2	Comparative Method		
	Positive	Negative	Total
Positive			
Negative			
Total			

Percent Accuracy Calculation Result (list): _____ %

Acceptance criteria: ≥90 % overall agreement for detecting HSV 2 DNA when compared to the reference method. Yes No

If Yes, Conclusion:

The BD ProbeTec HSV Q^x Amplified DNA Assay was able to detect the presence or absence of HSV 2 DNA equally as well as the comparator assay. The BD ProbeTec HSV Q^x Amplified HSV 2 DNA Assay meets the verification standard.

If No, Conclusion:

The BD ProbeTec HSV Q^x Amplified DNA Assay was not able to detect the presence or absence of HSV 2 DNA equally as well as the comparator assay. The BD ProbeTec HSV Q^x Amplified HSV 2 DNA Assay does not meet the verification standard. Review protocol, procedures, mitigate and repeat, if necessary.

Precision (reproducibility)

BD ProbeTec HSV	Comparative Method <i>TRUE</i> Result		
	Positive	Negative	Total
Positive	True Pos (a)	False Pos (b)	a + b
Negative	False Neg (c)	False Neg (d)	c + d
Total	a + c	b + d	n

Precision Calculation Result (list): _____ %

Acceptance criteria: >95 % precision was obtained for detecting HSV 1 and 2 DNA when compared to the reference method. Yes No

If Yes, Conclusion:

The BD ProbeTec HSV Q^x Amplified DNA Assay passed the precision standard. The BD ProbeTec HSV Q^x Amplified HSV DNA Assays meet the verification standard.

If No, Conclusion:

The BD ProbeTec HSV Q^x Amplified DNA Assay did not pass the precision standard. Review protocol, procedures, mitigate and repeat, if necessary.

Reportable Range

Acceptance criteria: ≥90 % accuracy for detecting HSV 1 and 2 DNA when compared to the reference method and when some of the known positive specimens are at the upper and lower limits of the manufacturer's reportable range. Yes No

Reference Range

Acceptance criteria: Either data, peer-reviewed articles or the BD ProbeTec HSV Q^x Amplified DNA Assays package insert have established that "normal" for most healthy patient populations would be a result of "HSV DNA not detected by SDA" or negative *AND* this is the population served by this laboratory. Yes No

Overall Acceptance criteria: All of the acceptance criteria are marked as “Yes”. Yes
No

If Yes, Conclusion:

The BD ProbeTec HSV Q^x Amplified DNA Assays are validated and can be used routinely for patient results.

Yes No

If No, Conclusion:

If any area above is marked as “No”, then the parameter needs to undergo review and corrective action and then be repeated until the parameter involved meets a “Yes” result or the assay is not validated and cannot be routinely employed. Review protocol, procedures, mitigate and repeat, if necessary.

Approval Signatures

Approved By: _____ Date: _____
Analyst(s)

Print Name and Title

Approved By: _____ Date: _____
Technical Supervisor

Print Name and Title

Approved By: _____ Date: _____
Technical Consultant

Print Name and Title

Approved By: _____ Date: _____
Director

Print Name and Title

SECTION 7: REFERENCES

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Professor Ferrero is a recognized international expert and consultant in communicable disease control, prevention, diagnostic testing and laboratory science. He has provided consultation services to the CDC, U. S. Public Health Services, State of California, and the private sector and has served on a number of state and national advisory committees. Recently, he was a consultant to the President's Emergency Plan For AIDS Relief (PEPFAR) where working with CDC and the Vietnamese Ministry of Health he guided policy development for a national laboratory strategic plan for Vietnam. Professor Ferrero served as Deputy Public Health Director, responsible for the Disease Control and Prevention Division at San Joaquin County Public Health Services in Stockton where he also served as the public health laboratory director and STD Controller. Professor Ferrero is the Chair of the Region IX - IPP Laboratory Committee and a member of the National Chlamydia Committee. He holds a professorship at the University of the Pacific with campuses in San Francisco, Sacramento, and Stockton and also serves as the Executive Director for the nation's second largest public health laboratory association, the California Association of Public Health Laboratory Directors. Professor Ferrero has been Principle Investigator (PI) for numerous United States' Food and Drug Administration (FDA) and European CE Marking in vitro diagnostic device clinical trials as well as a Principle Investigator for CDC's Laboratory Response Network (LRN) diagnostics studies of Severe Acute Respiratory Syndrome (SARS) [diagnostics](#). He has lectured and consulted internationally. His Bachelor of Arts degree is in Microbiology with a minor in Chemistry. He received his graduate degree in Public Health from the University of California at Berkeley. Professor Ferrero has numerous publications in peer-reviewed journals and is a member of several national and international professional organizations.