DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Quidel Corporation
Ronald H. Lollar
Senior Director, Clinical and Regulatory Affairs
2005 East State Street, Suite 100
Athens, OH 45701

November 28, 2016

Re: K162451
Trade/Device Name: Solana® HSV 1+2/VZV Assay
Regulation Number: 21 CFR 866.3309
Regulation Name: Herpes virus nucleic acid-based cutaneous and mucocutaneous lesion panel
Regulatory Class: II
Product Code: PGI
Dated: August 31, 2016
Received: September 1, 2016

Dear Mr. Lollar:

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 Parts 801 and 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Stephen J. Lovell -S for

Uwe Scherf, M.Sc., Ph.D.
Director
Division of Microbiology Devices
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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: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
k162451

Device Name
Solana® HSV 1+2/VZV Assay

Indications for Use *(Describe)*
The Solana® HSV 1+2/VZV Assay is an in vitro diagnostic test, using isothermal amplification technology (helicase-dependent amplification, HDA), for the qualitative detection and differentiation of herpes simplex virus type 1, herpes simplex virus type 2, and varicella-zoster virus DNA isolated and purified from cutaneous or mucocutaneous lesion samples obtained from symptomatic patients suspected of active herpes simplex virus 1, herpes simplex virus 2 and/or varicella-zoster infection. The Solana® HSV 1+2/VZV Assay is intended to aid in the diagnosis of herpes simplex virus 1, herpes simplex virus 2 and varicella-zoster virus active cutaneous or mucocutaneous infections. Negative results do not preclude herpes simplex virus 1, herpes simplex virus 2 and varicella-zoster virus infections and should not be used as the sole basis for diagnosis, treatment or other management decisions. The Solana® HSV 1+2/VZV Assay is intended for use only with the Solana® instrument.

Warning: The Solana® HSV 1+2/VZV Assay is not intended for use with cerebrospinal fluid or to aid in the diagnosis of HSV or VZV infections of the central nervous system (CNS). The Solana® HSV 1+2/VZV Assay is not intended for use in prenatal screening.

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.**

**510(k) Summary**

**Applicant:**

Quidel Corporation
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San Diego, California 92130
Telephone: 858-552-7910
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**Contact Information:**

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**Date of preparation of 510(k) summary:**

August 31, 2016

**A. 510(k) Number:**

k162451

**B. Purpose for Submission:**

To obtain substantial equivalence for the Solana® HSV 1+2/VZV Assay when performed on the Solana® instrument

**C. Measurand:**

HSV-1: US7: glycoprotein I

HSV-2: noncoding region between UL47: VP13/14 and UL48: VP16

VZV: ORF6: DNA-helicase primase

**D. Type of Test:**

**510(k) Summary**

Helicase-dependent amplification (HDA)

**E. Applicant:**

Quidel Corporation

**F. Proprietary and Established Names:**

Solana® HSV 1+2/VZV Assay

**G. Regulatory Information:**

**Table 1. Regulatory Information**

| Product Code | Classification | Regulation Section | Panel |
|---|---|---|---|
| PGI – Herpes Virus (VZV, HSV-1, HSV-2) DNA Detection Assay for Cutaneous and Mucocutaneous Lesion Samples | Class II (Special Controls) | 21 CFR 866.3309 – Herpes virus nucleic acid-based cutaneous and mucocutaneous lesion panel | Microbiology (83) |

**H. Intended Use:**

1. Intended Use(s):

The Solana® HSV 1+2/VZV Assay is an in vitro diagnostic test, using isothermal amplification technology (helicase-dependent amplification, HDA), for the qualitative detection and differentiation of herpes simplex virus type 1, herpes simplex virus type 2, and varicella-zoster virus DNA isolated and purified from cutaneous or mucocutaneous lesion samples obtained from symptomatic patients suspected of active herpes simplex virus 1, herpes simplex virus 2 and/or varicella-zoster infection. The Solana® HSV 1+2/VZV Assay is intended to aid in the diagnosis of herpes simplex virus 1, herpes simplex virus 2 and varicella-zoster virus active cutaneous or mucocutaneous infections. Negative results do not preclude herpes simplex virus 1, herpes simplex virus 2 and varicella-zoster virus infections and should not be used as the sole basis for diagnosis, treatment or other management decisions.

**510(k) Summary**

The Solana® HSV 1+2/VZV Assay is intended for use only with the Solana® instrument.

Warning: The Solana® HSV 1 + 2/VZV Assay is not intended for use with cerebrospinal fluid or to aid in the diagnosis of HSV or VZV infections of the central nervous system (CNS). The Solana® HSV 1 + 2/VZV Assay is not intended for use in prenatal screening.

2. Indication(s) for Use:

   Same as intended Use

3. Special conditions for use statement(s):

   - For *in vitro* diagnostic use only
   - For prescription use only

4. Special instrument requirements:

   Solana® instrument

## I. Device Description:

The Solana® HSV 1+2/VZV Assay amplifies and detects viral DNA isolated from cutaneous or mucocutaneous lesion samples obtained from symptomatic patients suspected of active herpes simplex virus 1, herpes simplex virus 2 and/or varicella-zoster infection.

The assay consists of two (2) major steps: 1) specimen preparation, and 2) amplification and detection of target sequence specific to HSV-1, HSV-2 and/or VZV using isothermal Helicase-Dependent Amplification (HDA) in the presence of target-specific fluorescence probe.

Patient specimen is transferred to a Process Tube, subjected to heat treatment at 95°C for 5 minutes and mixed and vortexed. The processed sample is transferred to a Reaction Tube and mixed. The Reaction Tube contains lyophilized HDA reagents, dNTPs, primers and probes. Once rehydrated with the diluted sample, the Reaction Tube is placed in Solana for amplification and detection of specific target sequence. In Solana, the target sequences are amplified by HSV-1, HSV-2 and/or VZV specific primers and detected by HSV-1, HSV-2 and/or VZV specific fluorescence probes included in the Reaction Tube. A competitive process control (PRC) is included in the Process Tube to monitor sample processing, inhibitory substances in clinical samples, reagent failure or device failure. The PRC target is amplified by specific primers and detected by a PRC specific fluorescence probe.

**510(k) Summary**

The target and PRC probes are labeled with a quencher on one end and a fluorophore on the other end. In addition, the target and PRC probes carry a ribonucleic acid. Upon annealing to HSV-1, HSV-2, VZV or PRC amplicons, the fluorescence probes are cleaved by RNaseH2 and the fluorescence signal increases due to physical separation of fluorophore from quencher. Solana measures and interprets the fluorescent signal, using on-board method-specific algorithms. Solana will then report the test results to the user on its display screen, and the results can be printed via an attached printer.

**Materials Provided:**

Cat. #M302

48 Tests per Kit

**Table 2. Kit Components**

| Component | Quantity | Storage |
|---|---|---|
| Process Buffer Tubes | 48 tubes/kit 1.6 mL | 2°C to 8°C |
| Reaction Tubes | 48 tubes/kit | 2°C to 8°C |

**Materials required but not provided:**

- External controls for HSV-1, HSV-2, or VZV (e.g. Quidel Molecular HSV/VZ Control Set, which contains positive and negative controls, serves as an external processing and extraction control)
- Sterile DNase-free filter-blocked or positive displacement micropipettor tips
- Micropipettor
- Stopwatch or timer
- Scissors or a blade
- Heat block capable of 95° C ± 2° C temperature
- Solana workflow tray and transfer rack
- Solana Instrument
- Thermometer

**J. Substantial Equivalence Information:**

1. Predicate device name(s):

   Lyra® Direct HSV 1+2/VZV Assay

2. Predicate 510(k) number(s):
   K133448

**510(k) Summary**

3. Comparison with predicate:

**Table 3. Similarities**

| Item | Subject Device Solana® HSV 1+2/VZV Assay | Subject Device Lyra® Direct HSV 1 + 2/VZV Assay K133448 |
|---|---|---|
| Intended Use | The Solana® HSV 1+2/VZV Assay is an *in vitro* diagnostic test, using isothermal amplification technology (helicase-dependent amplification, HDA), for the qualitative detection and differentiation of herpes simplex virus type 1, herpes simplex virus type 2, and varicella-zoster virus DNA isolated and purified from cutaneous or mucocutaneous lesion samples obtained from symptomatic patients suspected of active herpes simplex virus 1, herpes simplex virus 2 and/or varicella-zoster infection. The Solana® HSV 1+2/VZV Assay is intended to aid in the diagnosis of herpes simplex virus 1, herpes simplex virus 2 and varicella-zoster virus active cutaneous or mucocutaneous infections. Negative results do not preclude herpes simplex virus 1, herpes simplex virus 2 and varicella-zoster virus infections and should not be used as the sole basis for diagnosis, treatment or other management decisions. The Solana® HSV 1+2/VZV Assay is intended for use only with the Solana® instrument.<br><br>Warning: The Solana® HSV 1 + 2/VZV Assay is not intended for use with cerebrospinal fluid or to aid in the diagnosis of HSV or VZV infections of | The Lyra® Direct HSV 1 + 2/VZV Assay is an *in vitro* multiplex Real-Time PCR test for qualitative detection and differentiation of herpes simplex virus type 1, herpes simplex virus type 2, and varicella-zoster virus DNA isolated and purified from cutaneous or mucocutaneous lesion samples obtained from symptomatic patients suspected of active herpes simplex virus 1, herpes simplex virus 2 and/or varicella-zoster infection. The Lyra® Direct HSV 1 + 2/VZV Assay is intended to aid in the diagnosis of herpes simplex virus 1, herpes simplex virus 2 and varicella-zoster virus active cutaneous or mucocutaneous infections. Negative results do not preclude herpes simplex virus 1, herpes simplex virus 2 and varicella-zoster virus infections and should not be used as the sole basis for diagnosis, treatment or other management decisions. The Lyra® Direct HSV 1 + 2/VZV Assay is not intended for use with cerebral spinal fluid. The |

**510(k) Summary**

| Table 3. Similarities | | |
|---|---|---|
| **Item** | **Subject Device** Solana® HSV 1+2/VZV Assay | **Subject Device** Lyra® Direct HSV 1 + 2/VZV Assay K133448 |
| | the central nervous system. The Solana® HSV 1 + 2/VZV Assay is not intended for use in prenatal screening. | Lyra® Direct HSV 1 + 2/VZV Assay is not intended for use in prenatal screening. The device is not intended for point-of-care use. |
| Detection Techniques | Multiplex assay using different reporter dyes for each target | Multiplex assay using different reporter dyes for each target |
| Identification of HSV-1, HSV-2, and VZV | Yes | Yes |
| Assay Results | Qualitative | Qualitative |
| Sample Types | cutaneous or mucocutaneous lesion swab specimens obtained from symptomatic patients | cutaneous or mucocutaneous lesion swab specimens obtained from symptomatic patients |
| Extraction Methods | Not required | Not required |

| Table 4. Differences | | |
|---|---|---|
| **Item** | **Subject Device** Solana® HSV 1+2/VZV Assay | **Subject Device** Lyra® Direct HSV 1 + 2/VZV Assay K133448 |
| Viral Target | HSV-1: US7: glycoprotein I<br><br>HSV-2: noncoding region between UL47: VP13/14 and UL48: VP16<br><br>VZV: ORF6: DNA-helicase primase | HSV-1: glycoprotein G<br><br>HSV-2: glycoprotein G<br><br>VZV: ORF6: DNA-helicase primase |

**510(k) Summary**

| Table 4. Differences | | |
|---|---|---|
| **Item** | **Subject Device** Solana® HSV 1+2/VZV Assay | **Subject Device** Lyra® Direct HSV 1 + 2/VZV Assay K133448 |
| Assay Methodology | Helicase-Dependent Amplification (HDA) detecting the presence or absence of viral DNA in clinical specimens | PCR-based system for detecting the presence or absence of viral DNA in clinical specimens |
| Amplification and Detection instruments | Solana® instrument | Life Technologies QuantStudio™ Dx, the Applied Biosystems® 7500 Fast Dx, or the Cepheid SmartCycler® II System |

**K. Standard/Guidance Document Referenced (if applicable):**

Not applicable

**L. Test Principle:**

Patient specimen is transferred to a Process Tube, subjected to heat treatment at 95°C for 5 minutes and mixed and vortexed. The processed sample is transferred to a Reaction Tube and mixed. The Reaction Tube contains lyophilized HDA reagents, dNTPs, primers and probes. Once rehydrated with the diluted sample, the Reaction Tube is placed in Solana for amplification and detection of specific target sequence. In Solana, the target sequences are amplified by HSV-1, HSV-2 and/or VZV specific primers and detected by HSV-1, HSV-2 and/or VZV specific fluorescence probes included in the Reaction Tube. A competitive process control (PRC) is included in the Process Tube to monitor sample processing, inhibitory substances in clinical samples, reagent failure or device failure. The PRC target is amplified by specific primers and detected by a PRC specific fluorescence probe.

The target and PRC probes are labeled with a quencher on one end and a fluorophore on the other end. In addition, the target and PRC probes carry a ribonucleic acid. Upon annealing to HSV-1, HSV-2, VZV or PRC amplicons, the fluorescence probes are cleaved by RNaseH2 and the fluorescence signal increases due to physical separation of fluorophore from quencher. Solana measures and interprets the fluorescent signal, using on-board

method-specific algorithms. Solana will then report the test results to the user on its display screen, and the results can be printed via an attached printer.

**M. Performance Characteristics:**

1. Analytical performance:

*a. Precision/Reproducibility:*

*Reproducibility*

The reproducibility of the Solana HSV 1+2/VZV Assay was evaluated at three laboratory sites. A reproducibility panel containing 30 contrived samples, manufactured as high negative samples (n=3; 1/18x or 1/27x LOD ($C_{20}$ – $C_{80}$ concentration)) for HSV-1 MacIntyre, HSV-2 G, and VZV Ellen, low positive samples (n=3; near the assay limit of detection) for HSV-1, HSV-2 and VZV, moderate positive samples (n=3; 3x LOD) for HSV-1, HSV-2 and VZV and negative samples (n=3) was used for the study. The samples were randomized and blind-coded within each panel, and the operator tested one (1) panel, together with three (3) positive and three (3) negative external controls, in three runs. The panels were run by two operators at each testing site for five (5) non-consecutive days.

**Table 5. Reproducibility Summary**

| HSV-1 MacIntyre | SITE | | | | | | Overall Percent Agreement | | 95% Confidence Interval |
|---|---|---|---|---|---|---|---|---|---|
| | Site #1 | | Site #2 | | Site #3 | | | | |
| | *Rate of Detection* | *% Agreement* | *Rate of Detection* | *% Agreement* | *Rate of Detection* | *% Agreement* | *Rate of Detection* | *% Agreement* | |
| High Negative ($3.50\times 10^1$ $TCID_{50}$/mL) | 11/30 | 36.7 | 5/30 | 16.7 | 14/30 | 46.7 | 30/90 | 33.3 | 24.5 to 43.6 |
| Low Positive ($6.30 \times 10^2$ $TCID_{50}$/mL) | 30/30 | 100 | 30/30 | 100 | 30/30 | 100 | 90/90 | 100 | 95.9 to 100 |
| Moderate Positive ($1.89 \times 10^3$ $TCID_{50}$/mL) | 30/30 | 100 | 30/30 | 100 | 30/30 | 100 | 90/90 | 100 | 95.9 to 100 |
| Negative | 0/30 | 100 | 0/30 | 100 | 0/30 | 100 | 0/90 | 100 | 95.9 to 100 |
| Positive Control | 30/30 | 100 | 30/30 | 100 | 30/30 | 100 | 90/90 | 100 | 95.9 to 100 |
| Negative Control | 0/30 | 100 | 0/30 | 100 | 0/30 | 100 | 0/90 | 100 | 95.9 to 100 |

## 510(k) Summary

| HSV-2 G | SITE | | | | | | Overall Percent Agreement | | 95% Confidence Interval |
|---|---|---|---|---|---|---|---|---|---|
| | Site #1 | | Site #2 | | Site #3 | | | | |
| | *Rate of Detection* | *% Agreement* | *Rate of Detection* | *% Agreement* | *Rate of Detection* | *% Agreement* | *Rate of Detection* | *% Agreement* | |
| High Negative ($3.71 \times 10^{2}$ $TCID_{50}$/mL) | 12/30 | 40 | 8/30 | 26.7 | 7/30 | 23.3 | 27/90 | 30.0 | 21.5 to 40.1 |
| Low Positive ($6.67 \times 10^{3}$ $TCID_{50}$/mL) | 30/30 | 100 | 30/30 | 100 | 30/30 | 100 | 90/90 | 100 | 95.9 to 100 |
| Moderate Positive ($2.00 \times 10^{4}$ $TCID_{50}$/mL) | 30/30 | 100 | 30/30 | 100 | 30/30 | 100 | 90/90 | 100 | 95.9 to 100 |
| Negative | 0/30 | 100 | 0/30 | 100 | 0/30 | 100 | 0/90 | 100 | 95.9 to 100 |
| Positive Control | 30/30 | 100 | 30/30 | 100 | 30/30 | 100 | 90/90 | 100 | 95.9 to 100 |
| Negative Control | 0/30 | 100 | 0/30 | 100 | 0/30 | 100 | 0/90 | 100 | 95.9 to 100 |
| **VZV Ellen** | **SITE** | | | | | | **Overall Percent Agreement** | | **95% Confidence Interval** |
| | **Site #1** | | **Site #2** | | **Site #3** | | | | |
| | *Rate of Detection* | *% Agreement* | *Rate of Detection* | *% Agreement* | *Rate of Detection* | *% Agreement* | *Rate of Detection* | *% Agreement* | |
| High Negative ($5.50 \times 10^{-3}$ $TCID_{50}$/mL) | 11/30 | 36.7 | 2/30 | 6.7 | 8/30 | 26.7 | 21/90 | 23.3 | 15.8 to 33.1 |
| Low Positive ($1.49 \times 10^{-1}$ $TCID_{50}$/mL) | 30/30 | 100 | 30/30 | 100 | 30/30 | 100 | 90/90 | 100 | 95.9 to 100 |
| Moderate Positive ($4.46 \times 10^{-1}$ $TCID_{50}$/mL) | 30/30 | 100 | 30/30 | 100 | 30/30 | 100 | 90/90 | 100 | 95.9 to 100 |
| Negative | 0/30 | 100 | 0/30 | 100 | 0/30 | 100 | 0/90 | 100 | 95.9 to 100 |
| Positive Control | 30/30 | 100 | 30/30 | 100 | 30/30 | 100 | 90/90 | 100 | 95.9to 100 |
| Negative Control | 0/30 | 100 | 0/30 | 100 | 0/30 | 100 | 0/90 | 100 | 95.9 to 100 |

The results suggest that there are no significant differences between different users using different instruments at different sites on different days.

*b. Linearity/assay reportable range:*

Not applicable – This assay is qualitative.

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

*Traceability:*

Not applicable. This assay is qualitative.

*Specimen Stability:*

**510(k) Summary**

A study was performed to demonstrate specimen stability in various transport media types: M4, M4RT, M5, M6, and UTM when stored at room temperature (30 °C) for up to 48 hours, ≤ -20 °C, or 2 to 8 °C for up to 7 days.

HSV-1, HSV-2, and VZV virus stocks (HSV-1 McIntyre, HSV-2 G, and VZV Ellen) were diluted to their respective 2x LOD concentrations in each in of five (5) transport medium pooled negative matrix (Remel M4, Remel M5, Remel M6, Remel M4RT or UTM transport medium).

The transport media systems containing the contrived samples were stored T at three different conditions: Condition 1 = room temperature (30 ± 2 °C) for 50 hours, Condition 2 = 2 to 8 °C for 8 days, and Condition 3 = -20 °C for 8 days.

For Condition 1, the specimens were stored at room temperature (30 ± 2 °C) and tested at 0, 24, 48, and 50 hours post-storage. For Condition 2, the specimens were stored at 2-8 °C and tested at Day 0, Day 1, Day 3, Day 4, Day 7, and Day 8 post-storage. For Condition 3, the specimens were stored at -20 °C and tested at Day 0, Day 1, Day 3, Day 4, Day 7, and Day 8 post-storage.

Based on this study, HSV-1, HSV-2, and VZV samples at 2x LOD were stable when stored in M4, M4-RT, M5, M6, and UTM negative matrix for up to 50 hours at 30 °C ± 2 °C. HSV-1, HSV-2, and VZV samples were stable when stored in M4, M4-RT, M5, M6, and UTM negative matrix for up to 8 days at 2° to 8 °C. HSV-1, HSV-2, and VZV samples were stable when stored in M4, M4-RT, M5, M6, and UTM negative matrix for up to 8 days at 2° to 8 °C.

*Controls:*

- External controls for HSV-1, HSV-2, or VZV (e.g. Quidel Molecular HSV/VZV Control Set, which contains positive and negative controls, serves as an external processing and extraction control) were run on the Solana HSV 1+2/VZV Assay each day of testing.

The assay controls are described as follows:

*a.* The *process control* is used to monitor sample processing, to detect HDA inhibitory specimens and to confirm the integrity of assay reagents and Solana instrument functionality. The process control is included in the Process Buffer tube.

*b.* The *external positive control* may be treated as a patient specimen. The control should be sampled and tested as if it were a specimen and processed as described in the Assay Procedure. The external positive control is intended to monitor substantial reagent and instrument failure.

*c.* The *external negative control* may be treated as a patient specimen. The control should be sampled and tested as if it were a specimen and processed as described in the Assay Procedure. The external negative control is used to detect reagent or environmental contamination (or carry-over) by HSV 1+2/VZV DNA or amplicon.

*d. Detection limit:*

The analytical sensitivity (limit of detection or LOD) of the Solana HSV 1+2/VZV Assay was determined using quantified ($TCID_{50}$/mL) cultures of two (2) HSV-1 strains, two (2) HSV-2 strains, and two (2) VZV strains, serially diluted in negative matrix. Each dilution was run as 20 replicates in the Solana HSV 1+2/VZV assay. Analytical sensitivity (LOD) is defined as the lowest concentration at which at least 95% of all replicates tested positive. The demonstrated LOD for each strain tested is shown below:

**Table 6. LOD Values**

| Virus | $TCID_{50}$/mL |
|---|---|
| HSV-1 MacIntyre | $6.30 \times 10^{2}$ |
| HSV-1 316 | $5.47 \times 10^{4}$ |
| HSV-2 G | $6.67 \times 10^{3}$ |
| HSV-2 COMP | $1.62 \times 10^{5}$ |
| VZV Ellen | $1.49 \times 10^{-1}$ |
| VZV 9939 | $1.65 \times 10^{2}$ |

*e. Analytical specificity:*

Cross Reactivity:

A study was performed to evaluate the performance of the Solana HSV 1+2/VZV Assay in the presence of sixty-four (64) organisms that might be found in lesion specimens. Each potentially cross-reactive microorganism was tested at clinically relevant levels of viruses and bacteria: $\geq 10^{6}$ CFU/mL or IFU/mL; viruses: $\geq 10^{5}$ copies (cp), viral particles (vp) or $TCID_{50}$/mL.

**510(k) Summary**

| Table 7. Potentially Cross-reactive Organisms | | | |
|---|---|---|---|
| **Organism** | **Test Concentration** | **Organism** | **Test Concentration** |
| *Acholeplasma laidlawi* | 7.10E+06 CFU/mL | *Klebsiella pneumoniae* | 1.61E+06 CFU/mL |
| *Acinetobacter calcoaceticus* | 9.27E+06 CFU/mL | *Lactobacillus acidophilus* | 2.49E+06 CFU/mL |
| Adenovirus 7 | 1.58E+05 $TCID_{50}$/mL | *Legionella pneumophila* | 1.76E+06 CFU/mL |
| *Bacteroides fragilis* | 1.19E+06 CFU/mL | Measles virus | 1.95E+05 $TCID_{50}$/mL |
| *Bordetella bronchiseptica* | 1.97E+06 CFU/mL | *Mobiluncus mulieris* | 2.54E+06 CFU/mL |
| *Bordetella pertussis* | 7.21E+06 CFU/mL | *Moraxella cartarrhalis* | 1.26E+06 CFU/mL |
| *Candida albicans* | 2.00E+06 CFU/mL | Mumps virus | 5.89E+05 $TCID_{50}$/mL |
| *Candida glabrata* | 3.93E+06 CFU/mL | *Mycoplasma hominis* | 1.30E+06 CFU/mL |
| *Chlamydia trachomatis* | 3.00E+06 CFU/mL | *Mycoplasma hyorhinis* | 6.60E+06 CFU/mL |
| *Chlamydophila pneumoniae* | 1.25E+06 IFU/mL | *Mycoplasma orale* | 3.08E+06 CFU/mL |
| *Clostridium perfringens* | 1.06E+06 CFU/mL | *Mycoplasma pneumoniae* | 3.16E+06 CFU/mL |
| Coronavirus OC43 | 8.51E+05 $TCID_{50}$/mL | *Mycoplasma salivarium* | 1.67E+06 CFU/mL |
| *Corynebacterium diphtheriae* | 1.51E+06 CFU/mL | *Neisseria gonorrhoeae* | 1.23E+06 CFU/mL |
| Coxsackievirus B4 | 3.16E+05 $TCID_{50}$/mL | Parainfluenza Type 1 | 3.97E+05 $TCID_{50}$/mL |
| Cytomegalovirus Towne VR-977 | 2.14E+05 $TCID_{50}$/mL | Parainfluenza Type 2 | 3.15E+05 $TCID_{50}$ /mL |
| Echovirus 11 | 2.14E+05 $TCID_{50}$/mL | Parainfluenza Type 3 | 2.56E+05 $TCID_{50}$/mL |
| *Enterococcus faecalis* | 3.45E+06 CFU/mL | Parainfluenza Type 4 | 1.37E+05 $TCID_{50}$/mL |
| Enterovirus 70 | 1.78E+05 $TCID_{50}$/mL | *Proteus mirabilis* | 1.19E+06 CFU/mL |
| Epstein Barr Virus | 1.34E+05 vp/mL | *Pseudomonas aeruginosa* | 1.32E+06 CFU/mL |

**510(k) Summary**

| Table 7. Potentially Cross-reactive Organisms | | | |
|---|---|---|---|
| **Organism** | **Test Concentration** | **Organism** | **Test Concentration** |
| *Escherichia coli* | 8.42E+06 CFU/mL | RSV A Long | 1.95E+05 $TCID_{50}$/mL |
| *Gardnerella vaginalis* | 1.20E+06 CFU/mL | RSV B Washington | 3.43E+05 $TCID_{50}$/mL |
| *Haemophilis influenza type A* | 5.33E+06 CFU/mL | Rubella Virus | 2.09E+05 $TCID_{50}$/mL |
| HBV synthetic DNA | 6.80E+05 cp/mL | *Salmonella enteriditis* | 5.40E+06 CFU/mL |
| HCV synthetic RNA | 1.96E+05 cp/mL | *Salmonella typhimurium* | 1.01E+06 CFU/mL |
| HHV-6 | 3.30E+05 $TCID_{50}$/mL | *Staphylococcus aureus* | 1.02E+06 CFU/mL |
| HHV-7 | 1.15E+05 $TCID_{50}$/mL | *Staphylococcus saprophyticus* | 2.00E+06 CFU/mL |
| HHV-8 | 1.26E+05 $TCID_{50}$/mL | *Streptococcus agalactiae* | 2.20E+06 CFU/mL |
| HIV purified RNA | 1.60E+05 cp/mL | *Streptococcus pneumoniae* | 2.18E+06 CFU/mL |
| hMPV A1 | 3.66E+05 $TCID_{50}$/mL | *Streptococcus pyogenes* | 1.29E+06 CFU/mL |
| HPV | 4.30E+05 cp/uL | *Toxoplasma gondii* | 1.06E+06 tachyzoites/mL |
| Influenza A/Mexico/4108/2009 | 2.88E+05 vp/mL | *Trichomonas vaginalis* | 1.00E+06 trophozoites/mL |
| Influenza B Hong Kong VR-791 | 1.91E+05 $TCID_{50}$/mL | *Ureaplasma uralyticum* | 1.23E+06 CFU/mL |

No cross-reactivity was observed with the sixty-four (64) microorganisms tested with the Solana HSV 1+2/VZV Assay.

Interference:

The performance of Solana HSV 1+2/VZV Assay was evaluated with potentially interfering substances that may be present in lesion specimens. A panel composed of twenty-six (26) substances was tested in the absence or presence of HSV-1, HSV-2, or VZV (MacIntyre, G, Ellen strains, respectively) at 2X LOD in the Solana HSV 1+2/VZV Assay. There was no evidence of interference caused by the substances tested at the concentrations shown below.

| **Table 8. Potential Interfering Substances and Concentrations Tested** | | | |
|---|---|---|---|
| **Substance** | **Test Concentration** | **Substance** | **Test Concentration** |
| Abreva | 7% | Female Urine | 7% |
| Acetamidophenol | 10 mg/mL | KY Jelly | 7% |
| Acyclovir | 7 mg/mL | Lanacane | 3.50% |
| Albumin | 3.3 mg/mL | Leukocytes | $2.5x10^5$ cells/mL |
| Blood/EDTA | 0.63% | Listerine | 7% |
| Carmex | 7% | Male Urine | 7% |
| Casein | 7 mg/mL | Miconazole 1 | 7% |
| Chlorpheniramine | 5 mg/mL | Miconazole 3 | 7% |
| Colgate | 7% | Mucin | 60 µg/mL |
| Cornstarch | 2.5 mg/mL | Preparation H | 7% |
| Dextromethorphan | 5 mg/mL | Releev | 7% |
| Douche | 7% | Seminal Fluid | 2% |
| Feces | 0.22% | Tioconazole 1 | 7% |

Analytical Reactivity (Inclusivity):

The inclusivity of the Solana HSV 1+2/VZV Assay was further evaluated by functional testing of viral strains in addition to those strains used in the LOD study. The clinical panel consisted of two (2) strains of HSV-1, three (3) strains of HSV-2, and five (5) strains of VZV at concentrations near the level of detection (LOD) of the assay.

| **Table 9. Inclusivity Strains** | | |
|---|---|---|
| Strain | $TCID_{50}$/mL | Inclusive (Yes or No) |
| HSV-1 Isolate #1 | $1.26 \times 10^3$ | Yes |
| HSV-1 Isolate #3 | $1.26 \times 10^3$ | Yes |
| HSV-2 Strain MS | $1.33 \times 10^4$ | Yes |
| HSV-2 Isolate #25 | $1.33 \times 10^4$ | Yes |

**510(k) Summary**

| **Table 9. Inclusivity Strains** | | |
|---|---|---|
| Strain | $TCID_{50}$/mL | Inclusive (Yes or No) |
| HSV-2 Isolate #32 | $1.33 \times 10^4$ | Yes |
| VZV Strain 82 | $8.05 \times 10^0$ | Yes |
| VZV Strain 130 | $2.41 \times 10^1$ | Yes |
| VZV Strain 275 | $8.05 \times 10^0$ | Yes |
| VZV Strain B | $2.41 \times 10^1$ | Yes |
| VZV Strain D | $8.05 \times 10^0$ | Yes |

*f. Assay cut-off:*

Not applicable.

2. Comparison studies:

*a. Method comparison with predicate device:*

Not applicable

*b. Matrix comparison:*

Not applicable

3. Clinical studies:

*a. Clinical Sensitivity:*

Performance characteristics of the Solana® HSV 1+2/VZV Assay were established during a prospective study between February and April 2016. One thousand sixty-two (1062) fresh lesion specimens, collected for herpes simplex/varicella-zoster identification, have been included in this study at three sites across the United States. A single specimen was collected per patient. The specimens were processed and tested with Solana® HSV 1+2/VZV Assay on the Solana® instrument at the sites. Testing of the comparator methods (culture with DFA) were performed at one central location.

**510(k) Summary**

Combined Data

Cutaneous Lesions

Two-hundred seventy-five (275) active cutaneous lesion specimens were cultured for HSV-1, using the FDA-cleared ELVIS cell culture system and were also tested with the subject device for HSV-1 viral DNA. Samples which gave HSV-2 positive results from the ELVIS method were excluded from the HSV-1 performance calculation because of the inability of the ELVIS method to distinguish an HSV-1 positive sample when HSV-2 was detected first (n=26). The table below details the HSV-1 results for the remaining two-hundred forty-nine (249) specimens.

**Table 10. HSV-1 Results**

| | **Comparator: ELVIS® HSV ID and D³ Typing Test** | | |
|---|---|---|---|
| **Solana HSV 1 + 2/VZV Assay** | Positive | Negative | Total |
| Positive | 22 | 5* | 27 |
| Negative | 0 | 222 | 222 |
| Total | 22 | 227 | 249 |
| | | | **95% CI** |
| Sensitivity | 22/22 | 100% | 85.1% to 100% |
| Specificity | 222/227 | 97.8% | 95.0% to 99.1% |

* Three (3) of the five (5) positives was positive by an additional RT-PCR assay.

Two-hundred seventy-five (275) active cutaneous lesion specimens were cultured for HSV-2, using the FDA-cleared ELVIS cell culture system and were also tested with the subject device for HSV-2 viral DNA. The table below details the HSV-2 results for the two-hundred seventy-five (275).

**Table 11. HSV-2 Results**

| | **Comparator: ELVIS® HSV ID and D³ Typing Test** | | |
|---|---|---|---|
| **Solana HSV 1 + 2/VZV Assay** | Positive | Negative | Total |
| Positive | 24 | 14* | 28 |
| Negative | 2** | 235 | 237 |
| Total | 26 | 249 | 275 |
| | | | **95% CI** |
| Sensitivity | 24/26 | 92.3% | 75.9% to 97.9% |
| Specificity | 235/249 | 94.4% | 90.8% to 96.6% |

* Thirteen (13) of the fourteen (14) positives were positive by an additional RT-PCR assay.

** Two (2) of the two (2) negatives were positive by an additional RT-PCR assay.

**510(k) Summary**

Two-hundred and seventy-five (275) active cutaneous lesion specimens were cultured for VZV using the H&V mixed cells with DFA cell culture systems and were also tested with the subject device for VZV viral DNA. Due the presence of either HSV-1 or HSV-2, fifty-one (51) specimens have been excluded from analysis. Two (2) specimens were contaminated or had toxic cultures. These fifty-three (53) specimens have been excluded from analysis. The table below details the VZV results for the remaining two-hundred and twenty-two (222) specimens.

**Table 12. VZV Results**

| | **Comparator: DSFA and Culture with DFA** | | |
|---|---|---|---|
| **Solana HSV 1 + 2/VZV Assay** | Positive | Negative | Total |
| Positive | 22 | 7* | 29 |
| Negative | 0 | 193 | 193 |
| Total | 22 | 200 | 222 |
| | | | **95% CI** |
| Sensitivity | 22/22 | 100% | 85.1% to 100% |
| Specificity | 193/200 | 96.5% | 93.0% to 98.3% |

* Six (6) of the seven (7) positives were positive by an additional RT-PCR assay.

Mucocutaneous Lesions

Six-hundred twenty-one (621) active mucocutaneous lesion specimens were cultured for HSV-1, using the FDA-cleared ELVIS cell culture system and were also tested with the subject device for HSV-1 viral DNA. Seven (7) specimens were contaminated in the ELVIS cell culture. Two (2) specimens were invalid in Solana HSV 1 + 2/VZV Assay. Two (2) specimens were contaminated and invalid. Samples which gave HSV-2 positive results from the ELVIS method were excluded from the HSV-1 performance calculation because of the inability of the ELVIS method to distinguish an HSV-1 positive sample when HSV-2 was detected first (n=109). Thus, one hundred and twenty (120) specimens have been excluded from further analysis. The table below details the HSV-1 results for the remaining five-hundred and one (501) specimens.

**510(k) Summary**

| Table 13. HSV-1 Results | | | |
|---|---|---|---|
| | **Comparator: ELVIS® HSV ID and D³ Typing Test** | | |
| **Solana HSV 1 + 2/VZV Assay** | Positive | Negative | Total |
| Positive | 113 | 14* | 127 |
| Negative | 0 | 374 | 374 |
| Total | 113 | 388 | 501 |
| | | | **95% CI** |
| Sensitivity | 113/113 | 100% | 96.7% to 100% |
| Specificity | 374/388 | 96.4% | 94.0% to 97.8% |

* Six (6) of the fourteen (14) positives were positive by an additional RT-PCR assay.

Six-hundred twenty-one (621) active mucocutaneous lesion specimens were cultured for HSV-2, using the FDA-cleared ELVIS cell culture system and were also tested with the subject device for HSV-2 viral DNA. Seven (7) specimens were contaminated in the ELVIS cell culture. Two (2) specimens were invalid in Solana HSV 1 + 2/VZV Assay. Two (2) specimens were contaminated and invalid. These eleven (11) specimens have been excluded from further analysis. The table below details the HSV-2 results for the remaining six-hundred ten (610) specimens.

| Table 14. HSV-2 Results | | | |
|---|---|---|---|
| | **Comparator: ELVIS® HSV ID and D³ Typing Test** | | |
| **Solana HSV 1 + 2/VZV Assay** | Positive | Negative | Total |
| Positive | 108 | 14* | 122 |
| Negative | 1** | 487 | 488 |
| Total | 109 | 501 | 610 |
| | | | **95% CI** |
| Sensitivity | 108/109 | 99.1% | 95.0% to 99.8% |
| Specificity | 487/501 | 97.2% | 95.4% to 98.3% |

* Eleven (11) of the fourteen (14) positives were positive by an additional RT-PCR assay.

** One (1) of one (1) negative was positive by an additional RT-PCR assay.

Six-hundred twenty one (621) active mucocutaneous lesion specimens were cultured for VZV using the H&V mixed cells with DFA cell culture systems and were also tested with the subject device for VZV viral DNA. Due the presence of either HSV-1 or HSV-2, two hundred thirty-six (236) specimens have been excluded from analysis. Nine (9) specimens were contaminated in culture, and four (4) specimens were invalid in Solana HSV 1 + 2/VZV Assay. These two hundred forty-nine (249) specimens have been excluded from analysis. The

table below details the VZV results for the remaining three hundred seventy-two (372) specimens.

**Table 15. VZV Results**

| | **Comparator: DSFA and Culture with DFA** | | |
|---|---|---|---|
| **Solana HSV 1 + 2/VZV Assay** | Positive | Negative | Total |
| Positive | 4 | 5* | 9 |
| Negative | 0 | 363 | 363 |
| Total | 4 | 368 | 372 |
| | | | **95% CI** |
| Sensitivity | 4/4 | 100% | 51.0% to 100% |
| Specificity | 363/368 | 98.6% | 96.9% to 99.4% |

* One (1) of the five (5) positives was positive by an additional RT-PCR assay.

**Note**: The data presented for the detection of VZV is consistent with limited presence of VZV in mucocutaneous lesions. The use of mucocutaneous lesions has no discernible impact on the performance characteristics of Solana HSV 1 + 2/VZV Assay.

Uncategorized Lesions

One hundred sixty-six (166) active lesion specimens (not categorized as cutaneous or mucocutaneous) were cultured for HSV-1, using the FDA-cleared ELVIS cell culture system and were also tested with the subject device for HSV-1 viral DNA. Samples which gave HSV-2 positive results from the ELVIS method were excluded from the HSV-1 performance calculation because of the inability of the ELVIS method to distinguish an HSV-1 positive sample when HSV-2 was detected first (n=18). The table below details the HSV-1 results for the remaining one hundred and forty-eight (148) specimens.

**Table 16. HSV-1 Results**

| | **Comparator: ELVIS® HSV ID and D³ Typing Test** | | |
|---|---|---|---|
| **Solana HSV 1 + 2/VZV Assay** | Positive | Negative | Total |
| Positive | 25 | 3* | 28 |
| Negative | 0 | 120 | 120 |
| Total | 25 | 123 | 148 |
| | | | **95% CI** |
| Sensitivity | 22/22 | 100% | 86.7% to 100% |
| Specificity | 120/123 | 97.6% | 93.1% to 99.2% |

* Three (3) of the three (3) positives was positive by an additional RT-PCR assay.

**510(k) Summary**

One hundred sixty-six (166) active lesion specimens (not categorized as cutaneous or mucocutaneous) were cultured for HSV-2, using the FDA-cleared ELVIS cell culture system and were also tested with the subject device for HSV-2 viral DNA. The table below details the HSV-2 results for the one hundred sixty-six (166).

**Table 17. HSV-2 Results**

| | **Comparator: ELVIS® HSV ID and D³ Typing Test** | | |
|---|---|---|---|
| **Solana HSV 1 + 2/VZV Assay** | Positive | Negative | Total |
| Positive | 18 | 5* | 23 |
| Negative | 0 | 143 | 143 |
| Total | 18 | 148 | 166 |
| | | | **95% CI** |
| Sensitivity | 18/18 | 100% | 82.4% to 100% |
| Specificity | 143/148 | 96.6% | 92.3% to 98.6% |

* Five (5) of the five (5) positives were positive by an additional RT-PCR assay.

One hundred sixty-six (166) active lesion specimens (not categorized as cutaneous or mucocutaneous) were cultured for VZV using the H&V mixed cells with DFA cell culture systems and were also tested with the subject device for VZV viral DNA. Due the presence of either HSV-1 or HSV-2, forty-six (46) specimens have been excluded from analysis. One (1) specimen was contaminated in culture. These forty-seven (47) specimens have been excluded from analysis. The table below details the VZV results for the remaining one hundred nineteen (119) specimens.

**Table 18. VZV Results**

| | **Comparator: DSFA and Culture with DFA** | | |
|---|---|---|---|
| **Solana HSV 1 + 2/VZV Assay** | Positive | Negative | Total |
| Positive | 17 | 6* | 23 |
| Negative | 0 | 96 | 96 |
| Total | 17 | 102 | 119 |
| | | | **95% CI** |
| Sensitivity | 17/17 | 100% | 81.6% to 100% |
| Specificity | 96/102 | 94.1% | 87.8% to 97.3% |

* Five (5) of the six (6) positives were positive by an additional RT-PCR assay.

**510(k) Summary**

*b. Clinical specificity:*

See Section 3a.

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

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values:

The expected values of the Solana HSV 1+2/VZV Assay were established during a prospective study conducted between February and May 2016. One thousand sixty-two (1062) specimens have been included in this study at three (3) sites across the United States. A single specimen was collected per patient. The specimens were processed and tested with Solana HSV 1+2/VZV Assay on the Solana instrument at the sites.

The expected value of HSV-1, HSV-2, and VZV with the Solana HSV 1+2/VZV Assay has been calculated for the combined sites based on the category of specimen (cutaneous, mucocutaneous, or uncategorized lesion source) and the age of the patient.

**Table 19. Combined Study – Expected Values (Cutaneous) (N=273)**

| | HSV- 1 | | | HSV-2 | | | VZV | | |
|---|---|---|---|---|---|---|---|---|---|
| Age | Total # | Total Positive | Prevalence | Total # | Total Positive | Prevalence | Total # | Total Positive | Prevalence |
| ≤ 5 years | 9 | 1 | 11.1% | 9 | 0 | N/A | 9 | 4 | 44.4% |
| 6 to 21 years | 43 | 10 | 23.3% | 43 | 4 | 9.3% | 43 | 0 | N/A |
| 22 to 59 years | 180 | 16 | 8.9% | 180 | 26 | 14.4% | 180 | 19 | 10.6% |
| ≥ 60 years | 43 | 0 | N/A | 43 | 8 | 18.6% | 43 | 6 | 14.0% |

**Table 20. Expected Values (Cutaneous) (N=273)**

| | HSV- 1 | | | HSV-2 | | | VZV | | |
|---|---|---|---|---|---|---|---|---|---|
| | Total # | Total Positive | Prevalence | Total # | Total Positive | Prevalence | Total # | Total Positive | Prevalence |
| Genital - penis | 103 | 10 | 9.7% | 103 | 18 | 17.5% | 103 | 1 | 1.0% |
| skin lesion | 170 | 17 | 10.0% | 170 | 19 | 11.2% | 170 | 28 | 16.5% |

**510(k) Summary**

**Table 21. Combined Study – Expected Values (Mucocutaneous) (N=617)***

| | HSV- 1 | | | HSV-2 | | | VZV | | |
|---|---|---|---|---|---|---|---|---|---|
| Age | Total # | Total Positive | Prevalence | Total # | Total Positive | Prevalence | Total # | Total Positive | Prevalence |
| ≤ 5 years | 21 | 4 | 19.0% | 21 | 0 | N/A | 21 | 1 | 4.8% |
| 6 to 21 years | 158 | 41 | 25.9% | 158 | 29 | 18.4% | 158 | 0 | N/A |
| 22 to 59 years | 385 | 74 | 19.2% | 385 | 89 | 23.1% | 385 | 8 | 2.1% |
| ≥ 60 years | 53 | 11 | 20.8% | 53 | 5 | 9.4% | 53 | 1 | 1.9% |

* Four (4) specimens were invalid and removed from analysis

**Table 22. Expected Values (Mucocutaneous) (N=619)***

| | HSV- 1 | | | HSV-2 | | | VZV | | |
|---|---|---|---|---|---|---|---|---|---|
| | Total # | Total Positive | Prevalence | Total # | Total Positive | Prevalence | Total # | Total Positive | Prevalence |
| Anorectal | 26 | 7 | 26.9% | 26 | 7 | 26.9% | 26 | 1 | 3.8% |
| genital – vaginal/cervical | 449 | 80 | 17.8% | 449 | 112 | 24.9% | 449 | 5 | 1.1% |
| Nares | 23 | 5 | 21.7% | 23 | 1 | 4.3% | 23 | 3 | 13.0% |
| Ocular | 7 | 2 | 28.6% | 7 | 0 | N/A | 7 | 1 | 14.3% |
| Oral lesion | 112 | 36 | 32.1% | 112 | 3 | 2.7% | 112 | 0 | N/A |

* Four (4) specimens were invalid and removed from analysis

**Table 23. Combined Study – Expected Values (Uncategorized Lesion Source) (N=166)**

| | HSV- 1 | | | HSV-2 | | | VZV | | |
|---|---|---|---|---|---|---|---|---|---|
| Age | Total # | Total Positive | Prevalence | Total # | Total Positive | Prevalence | Total # | Total Positive | Prevalence |
| ≤ 5 years | 11 | 1 | 9.1% | 11 | 0 | N/A | 11 | 0 | N/A |
| 6 to 21 years | 28 | 10 | 35.7% | 28 | 0 | N/A | 28 | 2 | 7.1% |
| 22 to 59 years | 89 | 15 | 16.9% | 89 | 18 | 20.2% | 89 | 14 | 15.7% |
| ≥ 60 years | 38 | 2 | 5.3% | 38 | 5 | 13.2% | 38 | 8 | 21.1% |

**N. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:**

Instrument: Solana™ Instrument

**O. System Descriptions:**

1. Modes of Operation:

The Solana instrument heats each reaction tube to 64°C. If present, the target sequence is amplified by HSV-1, HSV-2 and/or VZV specific primers and detected by HSV-1, HSV-2 and/or VZV specific fluorescence probes included in the Reaction Tube. Each probe has a florescent dye of specific wavelength. The target probes are labeled with a quencher on one end and a fluorophore on the other end. In addition, the target probes carry a ribonucleic acid. Upon annealing to the respective amplicons, the fluorescence probes are cleaved by RNaseH2 and the fluorescence signal increases due to physical separation of fluorophore from quencher. The Solana instrument measures and interprets the fluorescent signal, using on-board method-specific algorithms. Solana instrument will then report the test results to the user on its display screen, and it can print out the results via a printer.

2. Software:

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes ____X____ No _____

**P. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10, 21 CFR 801.109, and the special controls.