***NVML Microbiology IQCP ImmunoCard STAT ! EHEC.***

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| **Facility:** NVML 750 West High St. Lima, OH |
| **Test System: *Meridian***  Package insert (PI) contains system performance data and describes testing principle and procedure, QC recommendations and limitations. The PI is located in the Microbiology cabinet. No specific limitations were noted in the PI that would affect the use of this test for our patient population; and no risks were identified upon review of the PI.  The manufacturer recommends the EHEC external controls (supplied in kit) be performed upon receipt of the kit and upon opening each kit. External controls should also be performed in accordance with local, state, and federal accrediting organizations, as applicable. A control zone on each testing device is a procedural control to assure that the sample has migrated sufficiently in the device to permit a valid test result to be read.  Manufacturer alerts and bulletins are located in the Microbiology cabinet.  No risks were identified upon review of any alert/bulletin. |
| **Test System Primary SOPs include:**  nvml.micro.aff.026.EHEC |
| **Historical Quality Review:**  Review of verification Data performed for the EHEC test kit (2012) showed no failures of positive and negative external controls or internal controls. 20 day QC was performed in 2014. Verification testing is filed in the Microbiology cabinet. Review of quality control for the past year  Showed new lot /shipment external QC check was performed 4 times and new kit external QC was performed over 60 times.  0% failures of external QC were noted  0% failure of internal QC was noted each day of patient testing. |

**Information Used to Conduct Risk Assessment:**

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| **Regulatory and Accreditation Requirements:** |
| **Checklist from Accrediting Agency:**  CAP: MIC 14583 |
| **Method verification:**  nvml.micro.aff.026.EHEC Verification performed 2012. 20 day QC performed 2014 |
| **Training of personnel:**  Completion of training documented in CAP Competency Program. |
| **Competency Assessment:**  Competency assessment records in CAP Competency Program. |
| **Proficiency Testing:**  Rotate personnel; all personnel review results. Proficiency testing records filed in CAP Survey Binder and CAP Competency Program. |
| **Quality Control:**  An IQCP has been developed to modify the quality control procedures for the STAT! EHEC test kit. Internal controls will be monitored as testing occurs and also recorded. External QC will be performed with new lot/shipments and upon opening a new box of test kits and recorded. |

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| **Test System Information:** |
| **Manufacturer:**   * The Package inserts are filed in the Microbiology cabinet. * Manufacturer informs users of any problems with test kits that are identified subsequent to release of the test with “product alerts”. Product alerts are located in the Microbiology cabinet. * Manufacturer has phone number available for reporting problems with the test kits. |
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| **Historic Review:**  Summary of in-house data for quality control of Immuno Card STAT! EHEC test kits.  QC has been performed as outlined in the following procedures; nvml.micro.aff. 026.EHEC  **EHEC controls** include one positive and one negative external control ran with each new lot/shipment and upon opening a new box. Review of data for the past year:  New Lot/ shipment QC performed for 4 lot/shipment checks and New Box External QC performed over 60 times in the past year. No failures of external QC or internal QC were experienced and no internal QC failures were noted when testing patient samples. |
| **Summary of corrected reports and physician complaints:**  There were no incidents of corrected reports or physician complaints as a result of defective test kits or unacceptable QC. |

**Risk Assessment: Identification of Potential Risks – ImmunoCard STAT! EHEC**

**Factors** Temperature Cleaning

Review of released results Clinical feedback Release from LIS to HIS

Verification QC failures

Receiving/Storage Expiration dates QC materials

Pre-analytical Analytical Post-analytical

**Operator Function** Training Competency assessment Proficiency testing Staffing levels

**Specimen** Identification Collection Transport Storage Volume

**Risk Assessment Tables**

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| **Frequency of occurrence:**  Unlikely (once every 2-3 years)  Occasional (once per year)  Probable (once per month)  Frequent (once a week) |  | |
| **Risk Level:** | |  |
| Risk level for any Risk Factor that is “Not Acceptable” must be addressed in the IQCP.  Risk level for any Risk Factor that is “Acceptable” may be included in the IQCP at the discretion of the Laboratory Director. | | |

**Risk Acceptability Matrix**

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| Probability of Harm | Negligible | Minor | Serious | Critical |
| Frequent | Not Acceptable | Not Acceptable | Not Acceptable | Not Acceptable |
| Probable | Acceptable | Not Acceptable | Not Acceptable | Not Acceptable |
| Occasional | Acceptable | Acceptable | Acceptable | Not Acceptable |
| Unlikely | Acceptable | Acceptable | Acceptable | Acceptable |

**Risk Acceptability Assignment**

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| **Risk Factor**  **(Possible Sources of Error)** | **Frequency of**  **occurrence** | **Severity of harm to**  **patient** | **Risk Level** |
| **Preanalytical** | | | |
| **Specimen:** | | | |
| Patient identification | probable | critical | Not Acceptable |
| Collection/container/volume | probable | minor | Acceptable |
| Transport | probable | negligible | Acceptable |
| Storage | probable | negligible | Acceptable |
| Volume | occasional | minor | Acceptable |
| **Analytical** | | | |
| **Testing Personnel:** | | | |
| Training | probable | negligible | Acceptable |
| Competency | occasional | negligible | Acceptable |
| Experience | occasional | negligible | Acceptable |
| Proficiency Testing | occasional | negligible | Acceptable |
| Staffing | occasional | negligible | Acceptable |
| **Reagents:** | | | |
| Shipping/receiving/storage | occasional | minor | Acceptable |
| Expiration dates | unlikely | minor | Acceptable |
| QC | unlikely | negligible | Acceptable |
| **Environment:** | | | |
| Temperature | unlikely | negligible | Acceptable |
| Cleaning | unlikely | negligible | Acceptable |
| **Test System:** | unlikely | negligible | Acceptable |
| Verification | unlikely | negligible | Acceptable |
| QC failures | unlikely | negligible | Acceptable |
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| **Postanalytical** | | | |
| **Test Results** | | | |
| Review of released results | occasional | minor | Acceptable |
| Release from LIS to HIS | occasional | minor | Acceptable |
| Clinician feedback | unlikely | negligible | Acceptable |
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**Risk Assessment**

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| **Possible Sources of Error** | | **How can identified sources of error be reduced?** |
| **Risk Factor** | **Possible Error** |
| **Preanalytical** | | |
| **Patient/specimen identification** | * Improper specimen procurement/ handling/processing | * Adhere to procedures: nvml.037 Labeling and Handling of Laboratory specimens, nvml.054 Outpatient Test Requests, nvml.058 Verification of Patient Identity nvml.073 Specimen Rejection Criteria and nvml.plating.005Rejection of Specimens that addresses patient identification and specimen collection, labeling, transport, storage and remedial actions to control improperly handled specimens or delayed specimens. * Annually review representative specimen processing errors with all staff involved with patient specimens.   During initial training and competency assessment, emphasize:   * Proper specimen handling/processing is the most critical part of any test |
| Collection/container/ volume |  | See above (Specimen) |
| Transport |  | See above (Specimen) |
| Storage |  | See above (Specimen) |
| **Analytical** | | |
| **2: Testing Personnel** | * Incompletely trained * Unaware of updated protocols | During initial training and competency assessment, emphasize:   * Key aspects of procedure, proper specimen source and use of correct test cartridge and broth. |
| Training |  | See above (Testing Personnel) |
| Competency |  | See above (Testing Personnel) |
| Proficiency Testing |  | * All appropriate staff read (and sign off) on PT sample critiques * Supervisor share any pertinent information from PT surveys with other staff, as appropriate |
| Staffing |  | * Supervisor to annually review appropriate staffing to support this test and appropriate turn- around- times. |
| **3: Reagents** |  | During initial training and competency assessment, emphasize standard rules to always:   * Take responsibility for using test cartridges appropriately (all staff) * Maintain cartridges at proper storage conditions * Check expiration dates * Check representative sample of cartridges for proper testing using appropriate external QC on new lots/shipments and newly opened test kit boxes. * All specimen specific QC parameters are controlled with internal QC. If there is a failure the assay will not be reported and testing will be repeated. |
| Receiving/storage | * Incorrect ordering * Damaged packaging | * Designated staff member(s) assigned to inventory (order/receipt) to ensure test supply is properly maintained and handled appropriately on receipt |
| Expiration dates |  | See above (Reagents) |
| **4: Environment** |  | During initial training and competency assessment, emphasize standard rules for:   * Take responsibility for any possible kit, environmental problem (out of the ordinary observation)(all staff) * Temperature recording (documented daily) Lab environmental conditions are appropriately maintained. |
| Temperature |  | See above (Environment) |
| Cleaning work area |  | Benches are properly cleaned after testing and if splash or spill of specimen occurs damaged. Proper discarding and decontamination protocols are followed for disposal of all testing materials. |
| **5: Test System** |  | During initial training and competency assessment, emphasize standard rules for:   * Take responsibility for any out of the ordinary observation with test cartridges * Inspecting each cartridge and diluent for contamination and any physical defects prior to use |
| **QC Failure** |  | If internal controls or external controls are not acceptable repeat testing /open new lot/ shipment. |
| **Postanalytical** |  | Criteria are defined to address failures associated with the Immuno card test system. |
| **6: Test Results** | | |
| Review reported results |  | * Supervisor maintains records of reporting errors and corrected reports; corrective action to address any potential issues. PI log is on line. |
| Clinician feedback |  | See above (Test Results) |
| Release from LIS to HIS |  | See above (Test Results)   * Incorporate suggestions into QA plan, as appropriate. |
|  |  | Criteria are defined for periodic review of results transfer related to the testing results entered from the technician. |

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| **Final QCP for ImmunoCard STAT! EHEC test kits** |
| Based on our Risk Assessment and Quality Assessment the QCP for immunoCard EHEC consists of following the instructions that are provided in explicit detail in the following procedures: nvml.micro.aff.026.EHEC. |
| Specimen collection/acceptability guidelines reviewed periodically. |
| Visual inspection of representative units of test cartridges for any physical defects or contamination upon receipt. |
| Staff training/competency reviewed yearly |
| Continual monitoring of storage environment for media |
| Review of manufacturer’s PIs and media alerts as received. |
| During initial training and competency assessment, instruct all staff about:   * Media storage conditions * The need for them to continually look for any defects, contamination or inconsistencies in test cartridges * Proper performance of internal and external QC * Unexpected errors investigated. |
| Whenever a problem or potential problem is identified or a complaint is issued investigation/remediation is performed. |

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| **Quality Assessment: Ongoing Monitoring for QCP Effectiveness (Performed by supervisor and/or section head)** | | |
| Reasons for QC failures, PT failures, and patient isolate reporting errors will be examined and addressed as needed in a new/updated risk assessment: 1) Has a new risk factor been identified? 2) Does this change the frequency of risk? 3) Does the risk factor change the potential severity of harm to patient? | | |
| Review of patient results for reporting errors and clinician complaints. Take corrective action and revise QCP as needed. | | |
| Review of manufacturer’s PIs, bulletins and updates as received and revise QCP as needed. | | |
| Review of EHEC procedures and revise as needed. | | |
| Regular review of Proficiency Testing results after each report is received from sponsor of PT program. Take corrective action and revise QCP if necessary when PT results are not acceptable. | | |
| Monthly review of all monitoring logs according to standard laboratory protocols. Take corrective action and revise QCP as needed. | | |
| Regular training and competency assessment according to standard laboratory protocols. Modify training and revise QCP as needed. | | |
| Continual participation in this institution’s quality program that addresses specimen handling and erroneous specimen labeling. Take corrective action and revise QCP as needed. | | |
| **This QCP has been reviewed and is approved by the laboratory director (as named on the CLIA license).** | **Signature** | **Date** |