***NVML Microbiology IQCP for MRSP, NASCP and Cdiff by PCR.***

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| **Facility:** NVML 750 West High St. Lima, OH |
| **Test System: *Cepheid GeneXpert***  Package insert (PI) contains system performance data and describes testing principle and procedure, QC recommendations and limitations. The PI is on a disk provided by Cepheid and is located in the GeneXpert Binder. 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.  No manufacturer recommendations are given for external QC. External controls may be used in accordance with local, state, and federal accrediting organizations, as applicable.  Manufacturer alerts and bulletins are located in the GeneXpert Binder.  No risks were identified upon review of any alert/bulletin. |
| **Test System Primary SOPs include:**  GeneXpert nvml.micro.GeneXPert.001.Inst  GeneXpert SA Nasal Complete nvml.micro.  GeneXpert.004SAnasalcomplete  GeneXpert Clostridium Difficile Assay nvml.micro.GenXpert.002.cdiff |
| **Historical Quality Review:**  MRSP test validation 9/21/2008, 10 day consecutive QC 3/4/2009. Historically external QC out 1 time in the past year and repeat of correct QC strain passed.  Cdiff test validation 12/20/2011, 10 day consecutive QC 11/27/2011, 20 day consecutive QC 7/24/2012. Historically QC out  NASCP test validation 9/17/2015, 20 day consecutive QC performed 7/20/2015. Historically QC out |

**Information Used to Conduct Risk Assessment:**

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| **Regulatory and Accreditation Requirements:** |
| **Checklist from Accrediting Agency:**  CAP:  COM.50200 (IQCP test list)  COM.50300 (RA)  COM.50400 (QCP approval)  COM.50500 (QCP defined)  COM.50600 (QA monitoring)  MIC 64810  MIC 64815 |
| **Method verification:**  **MRSP- 9/21/2008**  **CDiff-EPI- 12/20/2011**  **NASCP- 7/20/2015** |
| **Training of personnel:**  GeneXpert training 12/20/2011  Completion of training documented in Microbiology cabinet and CAP Competency Program. |
| **Competency Assessment:**  Competency assessment records filed 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 Cepheid, GeneXpert tests:  NASCP, MRSP and Cdiff Epi  Each Xpert cartridge produces a valid (positive or negative) test result, an ERROR result, or an INVALID result, depending on performance characteristics of the above internal controls that are run on every cartridge. Additionally, external controls are ran to assess performance of assays from new shipments, new lots, after major service events, in the event of a suspected or actual contamination event, after module replacement and after maintenance as necessary. Twenty day QC was performed on each of the indicated tests and is found on line under new test verification and also in the Microbiology cabinet. |

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| **Test System Information:** |
| **Manufacturer:**   * The Package inserts are on disks provided by Cepheid and are located in the GeneXpert Yearly QCP binder. * Manufacturer informs users of any problems with test cartridges that are identified subsequent to release of the test cartridges with “product alerts”. Product alerts are located in the GeneXpert yearly QC Binder. * Manufacturer has hotline available for reporting problems with defective media. |
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| **Historic Review:**  Summary of in-house data for quality control of GeneXpert test cartridges: Nares complete, MRSP and Cdiff-Epi.  QC has been performed as outlined in the following procedures: nvml.micro.GeneXPert.001.Inst, nvml.GenXpert.002.cdiff, nvml.micro.plating.GenXpertMRSA, nvml.micro.GeneXpert.004SAnasalcomplete.  **MRSP controls** include one positive and one negative control ran with each new lot/shipment. Review of data for the past year:  New Lot/ shipment QC performed for 11 lot/shipment checks. Major maintenance -4 times after module replacements( B4,B1,D3,D1)  No Software upgrades performed. No failures of external QC. No external QC failures were noted after system maintenance.  No internal QC failures were noted when testing patient samples.  **Cdiff** **controls** include one negative control and two positive controls ran with each new lot/shipment. Review of data for the past year: New Lot/shipment QC performed for 10 lot/shipment checks. There were 2 external QC failures the first on 8/17/15 was due to specimen contamination of organism ATCC9689 and upon repeat was acceptable. The second QC failure was performed on a module that failed internal QC and when repeated on a different module External QC was acceptable.  **NASCP controls** include two negative and two positive controls ran with each new lot/shipment. Review of data since 6/8/2015:  New lot/shipment QC performed for 2 lot/shipment checks. 1 external QC failed ATCC12228 due to lack of specimen on swab. Repeat of external QC was acceptable.  QC failures of external QC: 5% (which were within limits upon repeat testing).  **Expert check** found two modules that failed internal QC check, 1 module failed internal check while performing external QC and 1 module failed internal QC when performing a survey. These modules were replaced with calibrated modules and external QC performed for each test performed. External and Internal QC were acceptable on all replaced modules. No specimens were delayed and no patient harm was noted from these module failures. |
| **Summary of corrected reports and physician complaints:**  There were no incidents of corrected reports or physician complaints as a result of defective test modules or unacceptable QC. |

**Risk Assessment: Identification of Potential Risks – MRSP, Nares Complete, Cdiff-Epi**

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**Reported Results** Review of released results Clinician feedback Release from LIS to HIS

**Instrument**  Electric Maintenance Function checks

**Integrity** Receiving/Storage Expiration date QC

Pre-analytical Analytical Post-analytical

**Factors** Temperature PCR free

**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 |
| PCR free | unlikely | negligible | Acceptable |
| **Test System:** | | | |
| Electric | unlikely | negligible | Acceptable |
| Maintenance | unlikely | negligible | Acceptable |
| Function Checks | unlikely | negligible | Acceptable |
| **Postanalytical** | | | |
| **Test Results:** | | | |
| Review of released results | occasional | minor | Acceptable |
| Release from LIS to HIS | unlikely | negligible | Acceptable |
| Clinician feedback | occasional | minor | Acceptable |

**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 (cleaning), proper specimen source and use of correct test cartridge and diluent. |
| 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 available on all shifts. |
| **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. * All specimen specific QC parameters are controlled with internal QC. If there is a failure the assay will not deliver a patient result. The result will be “error” or “invalid”. |
| 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 instrument/ environmental problem (out of the ordinary observation)(all staff) * Equipment maintenance * Temperature recording (done automatically with continuous monitoring device) for test cartridges. Lab environmental conditions are appropriately maintained. * Electrical supply |
| Temperature |  | See above (Environment) |
| PCR free |  | Benches are properly cleaned after testing and if splash or spill of specimen occurs. Procedure to reduce cross contamination is used and gloves are changed at designated times of performing test prep. Test cartridges are self-contained. Amplicons cannot escape unless the cartridge’s integrity is damaged. Proper discarding and decontamination protocols are followed for disposal of all cartridges. |
| **5: Test System** |  | During initial training and competency assessment, emphasize standard rules for:   * Take responsibility for any out of the ordinary observation with instrumentation or cartridges * Inspecting each cartridge and diluent for contamination and any physical defects prior to use |
| Electric |  | During initial training and competency assessment, emphasize standard rules for:   * Electrical safety * Appropriate utilities are used in the laboratory to serve the GeneXpert. Internal temperature is automatically monitored by instrument. |
| Maintenance |  | Criteria are defined to address GeneXpert instrument maintenance. |
| Function checks |  | Criteria are defined to address failures associated with the GeneXpert system. |
| **Postanalytical** | | |
| **6: Test Results** |  | * Supervisor maintains records of reporting errors and corrected reports; corrective action to address any potential issues. PI log is on line. |
| Review reported results |  | See above (Test Results) |
| Clinician feedback |  | See above (Test Results)   * Incorporate suggestions into QA plan, as appropriate. |
| Release from LIS to HIS |  | Criteria are defined for periodic review of results transfer related to the GeneXpert and testing results from cartridges. |

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| **Final QCP for GeneXpert tests MRSP, Cdiff and NASCP** |
| Based on our Risk Assessment and Quality Assessment, the QCP for MRSP, NASCP and Cdiff consists of following the instructions that are provided in explicit detail in the following procedures |
| 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? | | |
| Daily 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. | | |
| Bi-annual review of MRSP, NASCP and Cdiff 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 equipment maintenance/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** |