**PROCEDURE: CEPHEID GX INTERFACES AUTOVERIFICATION PROCEDURE**

1. **OVERVIEW**

Autoverification is the process by which patient results are generated from interfaced instruments and sent to the LIS, where they are compared against laboratory-defined acceptance parameters. If the results fall within these defined parameters, the results are automatically released to patient reporting formats without any additional laboratory staff intervention. Any data that fall outside the defined parameters is reviewed by laboratory staff prior to reporting.

1. **SOFT TEST CODES**

CEVP\* – CSF Enterovirus PCR assay

CDPCR\*\* – C diff Toxin PCR

RFLUP\*\*\* – Rapid Flu PCR

RSVP\*\*\* – Rapid RSV PCR

FLRSV\*\*\* – Rapid Flu/RSV Combo PCR

MTBPC\* – TB PCR assay

GASPC\*\*\* - Group A Streptococcus PCR

GBSPC\*\*\*\*- Group B Streptococcus PCR

|  |  |
| --- | --- |
| \* | Performed at RIH only |
| \*\* | Performed at RIH & TMH |
| \*\*\* | Performed at RIH, TMH & NH |
| \*\*\*\* | Performed at RIH & NH |

2. **PROCEDURE FOR CEPHEID GENEXPERT INTERFACES**
   1. Prior to uploading results to LIS
      1. Review the run, scan for Invalid results
      2. Follow procedures for accepting/reviewing all quality control and standards.
   2. Adding Result Comments **prior** to UPLOAD.
      1. Any result comments should be added to the individual order numbers before a result is uploaded to LIS. This is done by entering a result comment through result entry:
         1. Right click on the result box of the test detail, a comment box will open up and canned message/comment can be added.
         2. Click OK
         3. Do not verify results at this point.
   3. \*\*Before ANY results are sent to Soft, be sure to check the Instrument Menu and be sure that Rec Date and Rec Time has been populated. If there are any blanks, bridge to Order Entry and Receive the specimens before beginning the autoverification process.
   4. UPLOAD RESULTS - results are OK
      1. “***View Results***” on Cepheid
      2. Click on ***Upload Test***
      3. A list of all pending and uploaded tests will display
      4. Check off order numbers to be sent to LIS
      5. Click on ***Upload*** at bottom of screen to send to LIS
      6. **Negatives**
         1. Autoverification is set up so that any ***negative*** results uploaded from the GeneXpert to Soft will Post to patient order number and autoverify.
      7. **Positives**
         1. Positives will transmit to Instrument Menu in Soft but will not autoverify. Tech will have to POST results from Instrument Menu.
   5. If the results are INVALID or ERROR do not Upload to Soft.
   6. Autoverification can be turned off at any time in Soft. Call the LIS dept and request the autoverification to be turned off. They can uncheck the Autopost box on Instrument Setup Menu.
   7. Documentation of Autoverification
      1. Autoverification should be validated yearly with Positive, Negative, and an INVALID.
      2. Date and time of autoverification can be viewed in SCC Soft through Lab Query.
   8. Monitoring Quality Control
      1. Quality control is run with each assay run. Results of quality control are reviewed before patient results are posted to LIS and autoverified.
   9. Results
      1. Review procedures must be implemented to determine valid and invalid results for each assay.
      2. Results will not post to patient record if specimen has not been collected and/or received.
3. **VALIDATION**
   1. Validation of the autoverification procedure should be done on a yearly basis or with any instrument or LIS changes.
      1. Complete *Form F6 – Cepheid Genexpert Autoverification QC*
   2. Validation can be done by printing screen prints from Soft to validate that the results did in fact post all the way through to the patient record.
   3. Screen prints needed:
      1. Instrument print out of values sent to Soft
      2. Instrument menu with all component tests verified
      3. Patient Instant report with the verified result

Validation of Interface Translations and Autoverification

Calculations, translations and /or rules involving reportable patient results must be rechecked and documented to ensure accuracy.

* Annually-CAP requirement
* Whenever a system change has occurred to the LIS system that may affect results-CAP requirement

All assays with calculations need to be validated. Manual/Non-LIS calculations should be compared to the LIS calculation results.

Toxigenic C Difficile PCR (CDPCR) ***\*\*screen print Instrument Tab, Lab Tab, and GeneXpert sheet***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Order # | Value/Range | **Instrument Results**  Toxigenic C diff Assay | **CDIFP Result**  Instrument Menu | Auto  Verified?  Y/N | Tech/Date |
|  | DETECTED | Toxigenic C diff POSITIVE |  |  |  |
|  | NOT DETECTED | Toxigenic C diff NEGATIVE |  |  |  |
|  | NOT DETECTED <3yrsOld | Toxigenic C diff NEGATIVE |  |  |  |
|  | INVALID | ERROR | N/A – not uploaded | N |  |

Enterovirus PCR (CEVP) ***\*\*screen print Instrument Tab, Lab Tab, and GeneXpert sheet***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Order # | Value/Range | **Instrument Results**  Expert EV | **CEVP Result**  Instrument Menu | Auto  Verified?  Y/N | Tech/Date |
|  | DETECTED | POSITIVE |  |  |  |
|  | NOT DETECTED | NEGATIVE |  |  |  |
|  | INVALID | INVALID | N/A- not uploaded |  |  |

Rapid Influenza PCR (RFLUP) ***\*\*screen print Instrument Tab, Lab Tab, and GeneXpert sheet***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Order # | Value/Range | **Instrument Results**  Flu A / Flu B | **Detail Result**  Instrument Menu | Auto  Verified?  Y/N | Tech/Date |
|  | DETECTED | POSITIVE (for 1) |  |  |  |
|  | NOT DETECTED | NEGATIVE (both) |  |  |  |
|  | INVALID | INVALID | N/A- not uploaded |  |  |

Rapid RSV PCR (RSVP) ***\*\*screen print Instrument Tab, Lab Tab, and GeneXpert sheet***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Order # | Value/Range | **Instrument Results**  RSV | **Detail Result**  Instrument Menu | Auto  Verified?  Y/N | Tech/Date |
|  | DETECTED | POSITIVE |  |  |  |
|  | NOT DETECTED | NEGATIVE |  |  |  |
|  | INVALID | INVALID | N/A- not uploaded |  |  |

Rapid Influenza/RSV Combo (FLRSV) *\*\*****screen print Instrument Tab, Lab Tab, and GeneXpert sheet***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Order # | Value/Range | **Instrument Results**  Flu A / Flu B / RSV | **Detail Result**  Instrument Menu | Auto  Verified?  Y/N | Tech/Date |
|  | DETECTED | POSITIVE (for 1) |  |  |  |
|  | NOT DETECTED | NEGATIVE (for all 3) |  |  |  |
|  | INVALID | INVALID | N/A- not uploaded |  |  |

Mycobacterium Tuberculosis PCR (MTBPC) ***\*\*screen print Instrument Tab, Lab Tab, and GeneXpert sheet***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Order # | Value/Range | **Instrument Results**  MTB-RIF | **Detail Result**  Instrument Menu | Auto  Verified?  Y/N | Tech/Date |
|  | DETECTED/ DETECTED | MTB DETECTED |  |  |  |
|  | DETECTED/ NOT DETECTED | MTB DETECTED |  |  |  |
|  | NOT DETECTED | MTB NOT DETECTED |  |  |  |
|  | INVALID | INVALD | N/A- not uploaded |  |  |

Group A Streptococcus PCR (GASPC)***\*\*screen print Instrument Tab, Lab Tab, and GeneXpert sheet***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Order # | Value/Range | **Instrument Results**  Group A Strep | **GASPC Result**  Instrument Menu | Auto  Verified?  Y/N | Tech/Date |
|  | DETECTED | DETECTED |  |  |  |
|  | NOT DETECTED | NOT DETECTED |  |  |  |
|  | INVALID | INVALID | N/A- not uploaded |  |  |

Group B Streptococcus PCR (GBSPC) ***\*\*screen print Instrument Tab, Lab Tab, and GeneXpert sheet***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Order # | Value/Range | **Instrument Results**  Group B Strep | **GBSPC Result**  Instrument Menu | Auto  Verified?  Y/N | Tech/Date |
|  | DETECTED | DETECTED |  |  |  |
|  | NOT DETECTED | NOT DETECTED |  |  |  |
|  | INVALID | INVALID | N/A – not uploaded |  |  |

Is this Annual Validation? YES / NO Was this Validation performed because of a Soft LIS system change? YES / NO

If SoftLab system change, Explain\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_