**PROCEDURE: BD MAX INTERFACE AUTOVERIFICATION**

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 CODE**

CDPCR\* – C diff Toxin PCR

ENTB/ENTBR\* – Basic Enteric GI PCR Panels

PARSC\* – Parasite screen PCR Panel

NAPAT\* – Pre-admit Nasal screen PCR Panel

VPPCR\*\*- Vaginitis PCR Panel

|  |  |
| --- | --- |
| \* | Performed at RIH only |
| \*\* | Performed at TMH only |

1. **PROCEDURE FOR BD MAX™ INTERFACE**
   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.

\*\*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.

* 1. UPLOAD RESULTS - review results to ensure they are OK
     1. Results are available on the “RESULTS” tab in the results window on the BD MAX™ System monitor.
     2. The BD MAX™ System automatically interprets the test results.
     3. Results that can be reported by the BD MAX™ System are:
        1. POS – Positive
        2. NEG – Negative
        3. UNR – Unresolved
        4. IND – Indeterminate
        5. INC – Incomplete Run
     4. **Negatives**
        1. Autoverification is set up so that any ***negative*** results uploaded from the BD MAX™ System to Soft will Post to patient order number and autoverify.
     5. **Positives**
        1. Positives will transmit to Instrument Menu in Soft but will not autoverify. Tech will have to POST results from Instrument Menu.
  2. If the results are UNR, IND and INC do not upload to Soft.
  3. 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.
  4. 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.
  5. 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.
  6. 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.

1. **VALIDATION**
   1. Validation of the autoverification procedure should be done on a yearly basis or with any instrument or LIS changes.
      1. Complete *Form F8 – BD Max 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:

* Instrument print out of values sent to Soft
* Instrument menu with all component tests verified
* Patient Instant report with the verified result

Validation of Interface Translations and Auto Verification

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 DIFF ASSAY (CDPCR)** ***\*\*screen print Instrument Tab, Lab Tab, and BD MAX 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 |  |  |  |
|  | INVALID | ERROR | N/A – not uploaded |  |  |
|  | NOT DETECTED <3yrs old | Toxigenic C diff NEGATIVE |  |  |  |

**ENTERIC BACTERIAL PANEL – Cary-Blair (ENTB)** ***\*\*screen print Instrument Tab, Lab Tab, and BD MAX sheet***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Order # | Value/Range | **Instrument Results**  Campy/Salmonella/Shigella/STEC | **Detail result**  Instrument Menu | Auto  Verified?  Y/N | Tech/Date |
|  | DETECTED | POSITIVE (For at least 1) |  |  |  |
|  | NOT DETECTED | NEGATIVE (For all 4) |  |  |  |
|  | INVALID | INVALID/UNRESOLVED | N/A – not uploaded |  |  |

**ENTERIC BACTERIAL PANEL – Fecal Swab (ENTBR)** ***\*\*screen print Instrument Tab, Lab Tab, and BD MAX sheet***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Order # | Value/Range | **Instrument Results**  Campy/Salmonella/Shigella/STEC | **Detail result**  Instrument Menu | Auto  Verified?  Y/N | Tech/Date |
|  | DETECTED | POSITIVE (For at least 1) |  |  |  |
|  | NOT DETECTED | NEGATIVE (For all 4) |  |  |  |
|  | INVALID | INVALID/UNRESOLVED | N/A – not uploaded |  |  |

**ENTERIC PARASITE PANEL – Total-Fix (PARSC)** ***\*\*screen print Instrument Tab, Lab Tab, and BD MAX sheet***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Order # | Value/Range | **Instrument Results**  Giardia/Cryptosporidum/E.histolytica | **Detail result**  Instrument Menu | Auto  Verified?  Y/N | Tech/Date |
|  | DETECTED | POSITIVE (For at least 1) |  |  |  |
|  | NOT DETECTED | NEGATIVE (For all 3) |  |  |  |
|  | INVALID | INVALID/UNRESOLVED | N/A – not uploaded |  |  |

**PREADMIT NASAL SCREEN – Copan Swab (NAPAT)** ***\*\*screen print Instrument Tab, Lab Tab, and BD MAX sheet***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Order # | Value/Range | **Instrument Results**  Staphylococcus aureus DNA/  Methicillin Resistant Staph aureus DNA | **Detail result**  Instrument Menu | Auto  Verified?  Y/N | Tech/Date |
|  | DETECTED | POSITIVE (For at least 1) |  |  |  |
|  | NOT DETECTED | NEGATIVE (For both) |  |  |  |
|  | INVALID | INVALID/UNRESOLVED | N/A – not uploaded |  |  |

**VAGINITIS PANEL – UVE (VPPCR)** ***\*\*screen print Instrument Tab, Lab Tab, and BD MAX sheet***

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Order # | Value/Range | **Instrument Results**  Bacterial Vaginosis/ Candida group/ Candida glabrata/ Candida krusei/ Trichomonas vaginalis | **Detail result**  Instrument Menu | Auto  Verified?  Y/N | Tech/Date |
|  | DETECTED | POSITIVE (For at least 1) |  |  |  |
|  | NOT DETECTED | NEGATIVE (For all 4) |  |  |  |
|  | INVALID | INVALID/UNRESOLVED | 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\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_