**Direct Observation** (Automated)

* Direct observation of routine patient test performance including (as applicable) patient identification and preparation, specimen collection, handling, processing and testing.
* Direct observation of performance of instrument maintenance and function checks.

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| **Hematology/XT4000i** | Competency observed?  | Comments |
| Performs instrument startup/shutdown as written in procedure | □ Yes □ No |  |
| Performs preventative maintenance as required | □ Yes □ No |  |
| Demonstrates proper handling/competency of quality control | □ Yes □ No |  |
| Runs controls according to procedure  | □ Yes □ No |  |
| Verifies QC is acceptable before reporting patients | □ Yes □ No |  |
| Takes appropriate action when QC is out of range | □ Yes □ No |  |
| Documents out of range controls and corrective action taken | □ Yes □ No |  |
| Verifies specimen integrity and volume prior to testing | □ Yes □ No |  |
| Documents corrective action if specimen is unacceptable | □ Yes □ No |  |
| Performs patient testing according to procedures | □ Yes □ No |  |
| Verifies patient results and records (prints) correctly | □ Yes □ No |  |
| Replaces, logs, and stores reagents correctly | □ Yes □ No |  |
| **Competent?** □ Yes □ No*(If no, document any corrective action)* | **Evaluator signature/date:** |
| **Hematology/Ruby** | Competency observed?  | Comments |
| Performs instrument startup/shutdown as written in procedure | □ Yes □ No |  |
| Performs preventative maintenance as required | □ Yes □ No |  |
| Demonstrates proper handling/competency of quality control | □ Yes □ No |  |
| Runs controls according to procedure  | □ Yes □ No |  |
| Verifies QC is acceptable before reporting patients | □ Yes □ No |  |
| Takes appropriate action when QC is out of range | □ Yes □ No |  |
| Documents out of range controls and corrective action taken | □ Yes □ No |  |
| Verifies specimen integrity and volume prior to testing | □ Yes □ No |  |
| Documents corrective action if specimen is unacceptable | □ Yes □ No |  |
| Performs patient testing according to procedures | □ Yes □ No |  |
| Verifies patient results and records (prints) correctly | □ Yes □ No |  |
| Replaces, logs, and stores reagents correctly | □ Yes □ No |  |
| **Competent?** □ Yes □ No*(If no, document any corrective action)* | **Evaluator signature/date:** |
| **Coagulation/CA-1500***PT/PTT* | Competency observed?  | Comments |
| Performs instrument startup/shutdown as written in procedure | □ Yes □ No |  |
| Performs preventative maintenance as required | □ Yes □ No |  |
| Demonstrates proper handling/competency of quality control | □ Yes □ No |  |
| Runs controls according to procedure | □ Yes □ No | 2 levels of controls every 8 hours |
| Verifies QC is acceptable before reporting patients | □ Yes □ No |  |
| Takes appropriate action when QC is out of range | □ Yes □ No |  |
| Documents out of range controls and corrective action taken | □ Yes □ No |  |
| Verifies specimen integrity and volume prior to testing | □ Yes □ No |  |
| Documents corrective action if specimen is unacceptable | □ Yes □ No |  |
| Performs patient testing according to procedures | □ Yes □ No |  |
| Verifies patient results and records (prints) correctly | □ Yes □ No |  |
| Replaces, logs, and stores reagents correctly | □ Yes □ No |  |
| **Competent?** □ Yes □ No*(If no, document any corrective action)* | **Evaluator signature/date:** |
| **Coagulation/CA-1500***D-dimer* | Competency observed?  | Comments |
| Performs instrument startup/shutdown as written in procedure | □ Yes □ No |  |
| Performs preventative maintenance as required | □ Yes □ No |  |
| Demonstrates proper handling/competency of quality control | □ Yes □ No |  |
| Runs controls according to procedure | □ Yes □ No | Controls run with every patient test |
| Verifies QC is acceptable before reporting patients | □ Yes □ No |  |
| Takes appropriate action when QC is out of range | □ Yes □ No |  |
| Documents out of range controls and corrective action taken | □ Yes □ No |  |
| Verifies specimen integrity and volume prior to testing | □ Yes □ No |  |
| Documents corrective action if specimen is unacceptable | □ Yes □ No |  |
| Performs patient testing according to procedures | □ Yes □ No |  |
| Verifies patient results and records (prints) correctly | □ Yes □ No |  |
| Replaces, logs, and stores reagents correctly | □ Yes □ No |  |
| **Competent?** □ Yes □ No*(If no, document any corrective action)* | **Evaluator signature/date:** |
| **Chemistry***c4000* | Competency observed?  | Comments |
| Performs instrument startup as written in procedure | □ Yes □ No |  |
| Performs preventative maintenance as required | □ Yes □ No |  |
| Demonstrates proper handling/competency of quality control and cals | □ Yes □ No |  |
| Runs controls according to procedure | □ Yes □ No | Two levels minimum every 24 hours of patient testing |
| Verifies QC is acceptable before reporting patients | □ Yes □ No |  |
| Takes appropriate action when QC is out of range | □ Yes □ No |  |
| Documents out of range controls and corrective action taken | □ Yes □ No |  |
| Verifies specimen integrity and volume prior to testing | □ Yes □ No |  |
| Documents corrective action if specimen is unacceptable | □ Yes □ No |  |
| Performs patient testing according to procedures | □ Yes □ No |  |
| Verifies patient results and records (prints) correctly | □ Yes □ No |  |
| Replaces, logs, and stores reagents correctly | □ Yes □ No |  |
| **Competent?** □ Yes □ No*(If no, document any corrective action)* | **Evaluator signature/date:** |
| **Chemistry***i1000* | Competency observed?  | Comments |
| Performs instrument startup/shutdown as written in procedure | □ Yes □ No |  |
| Performs preventative maintenance as required | □ Yes □ No |  |
| Demonstrates proper handling/competency of quality control | □ Yes □ No |  |
| Runs controls according to procedure | □ Yes □ No | Two levels minimum every 24 hours of patient testing |
| Verifies QC is acceptable before reporting patients | □ Yes □ No |  |
| Takes appropriate action when QC is out of range | □ Yes □ No |  |
| Documents out of range controls and corrective action taken | □ Yes □ No |  |
| Verifies specimen integrity and volume prior to testing | □ Yes □ No |  |
| Documents corrective action if specimen is unacceptable | □ Yes □ No |  |
| Performs patient testing according to procedures | □ Yes □ No |  |
| Verifies patient results and records (prints) correctly | □ Yes □ No |  |
| Replaces, logs, and stores reagents correctly | □ Yes □ No |  |
| **Competent?** □ Yes □ No*(If no, document any corrective action)* | **Evaluator signature/date:** |
| **Bacteriology***Vitek* | Competency observed?  | Comments |
| Stores cards, reagents and media properly | □ Yes □ No |  |
| Monitors any new lot for new lot QC  | □ Yes □ No | Cards, media |
| Runs QC according to protocols | □ Yes □ No | Weekly |
| Verifies QC is acceptable before reporting results | □ Yes □ No |  |
| Takes appropriate action when QC is out of range | □ Yes □ No |  |
| Verifies specimen integrity and source prior to testing | □ Yes □ No | Selects appropriate media |
| Documents action if specimen is unacceptable | □ Yes □ No |  |
| Performs patient testing according to protocol | □ Yes □ No |  |
| Verifies patient results and records correctly | □ Yes □ No |  |
| **Competent?** □ Yes □ No*(If no, document any corrective action)* | **Evaluator signature/date:** |
| **Bacteriology***Cepheid* | Competency observed?  | Comments |
| Performs instrument startup/shutdown as written in procedure | □ Yes □ No |  |
| Performs preventative maintenance as required | □ Yes □ No |  |
| Demonstrates proper handling/competency of quality control | □ Yes □ No |  |
| Runs controls according to procedure | □ Yes □ No | 30 day QC/new lot QC |
| Verifies QC is acceptable before reporting patients | □ Yes □ No |  |
| Takes appropriate action when QC is out of range | □ Yes □ No |  |
| Documents out of range controls and corrective action taken | □ Yes □ No |  |
| Verifies specimen integrity and source prior to testing | □ Yes □ No |  |
| Documents corrective action if specimen is unacceptable | □ Yes □ No |  |
| Performs patient testing according to procedures | □ Yes □ No |  |
| Verifies patient results and records (prints) correctly | □ Yes □ No |  |
| Replaces, logs, and stores reagents correctly | □ Yes □ No |  |
| **Competent?** □ Yes □ No*(If no, document any corrective action)* | **Evaluator signature/date:** |
| **Bacteriology***Bac-T-Alert* | Competency observed?  | Comments |
| Performs instrument startup/shutdown as written in procedure | □ Yes □ No |  |
| Performs preventative maintenance as required | □ Yes □ No |  |
| Verifies specimen integrity and source prior to testing | □ Yes □ No |  |
| Documents corrective action if specimen is unacceptable | □ Yes □ No |  |
| Correctly loads specimens into system | □ Yes □ No |  |
| **Competent?** □ Yes □ No*(If no, document any corrective action)* | **Evaluator signature/date:** |
| **Urinalysis***Clinitek Status* | Competency observed?  | Comments |
| Performs instrument startup/shutdown as written in procedure | □ Yes □ No |  |
| Performs preventative maintenance as required | □ Yes □ No |  |
| Demonstrates proper handling/competency of quality control | □ Yes □ No |  |
| Runs controls according to procedure | □ Yes □ No | Each day of patient testing |
| Verifies QC is acceptable before reporting patients | □ Yes □ No |  |
| Takes appropriate action when QC is out of range | □ Yes □ No |  |
| Documents out of range controls and corrective action taken | □ Yes □ No |  |
| Verifies specimen integrity and source prior to testing | □ Yes □ No |  |
| Documents corrective action if specimen is unacceptable | □ Yes □ No |  |
| Performs patient testing according to procedures | □ Yes □ No |  |
| Verifies patient results and records (prints) correctly | □ Yes □ No |  |
| Replaces, logs, and stores reagents correctly | □ Yes □ No |  |
| **Competent?** □ Yes □ No*(If no, document any corrective action)* | **Evaluator signature/date:** |
| **POCT***iSTAT* | Competency observed?  | Comments |
| Performs instrument startup/shutdown as written in procedure | □ Yes □ No |  |
| Performs preventative maintenance as required | □ Yes □ No |  |
| Demonstrates proper handling/competency of quality control | □ Yes □ No |  |
| Runs controls according to procedure | □ Yes □ No | 30 day QC/each new lot |
| Verifies QC is acceptable before reporting patients | □ Yes □ No |  |
| Takes appropriate action when QC is out of range | □ Yes □ No |  |
| Documents out of range controls and corrective action taken | □ Yes □ No |  |
| Verifies specimen integrity and source prior to testing | □ Yes □ No |  |
| Documents corrective action if specimen is unacceptable | □ Yes □ No |  |
| Performs patient testing according to procedures | □ Yes □ No |  |
| Verifies patient results and records (prints) correctly | □ Yes □ No |  |
| Replaces, logs, and stores reagents correctly | □ Yes □ No |  |
| **Competent?** □ Yes □ No*(If no, document any corrective action)* | **Evaluator signature/date:** |

I certify that I am fully trained and competent to perform the roles listed above.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Employee sign/date

I attest that the staff member listed above is fully trained and competent to perform the roles listed above.

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Laboratory manager sign/date