MICROBIOLOGY PERFORMANCE OF LABORATORY TESTS

☒ St. Joseph Medical Center, Tacoma, WA	☒ St. Anthony Hospital Gig Harbor, WA	☐ Harrison Medical Center, Bremerton, WA
☒ St. Francis Hospital, Federal Way, WA	☒ St. Elizabeth Hospital Enumclaw, WA	☐ Harrison Medical Center, Silverdale, WA
☒ St. Clare Hospital Lakewood, WA	☒ Highline Medical Center Burien, WA	☐ PSC

PURPOSE

To provide an overall view of Microbiology department testing.

STEPS

1. Each test and/or procedure will be performed and reported as detailed in the appropriate procedure. For all test procedures, including CLIA-waived, work instructions and policies will be written and followed according to the FDA and manufacturer's instructions.

2. No changes will be made in any test procedure without prior approval of the manager of the department and/or the medical director of the laboratory.

3. Each test run will be identified by recording the name of the person or persons performing the test in the LIS and dated. Any unusual results or sequence of unusual results will be referred to the manager for review.

4. All manual logbook entries must be made with ball-point pen. Corrections are made by putting a single line through the erroneous entry and then writing in the corrected entry, initialed and date. Correction fluid, i.e., "Whiteout" is not permitted.

5. If standards, reference materials or quality control samples are indicated for a procedure, test results will not be reported until they have been included and unless their values lie within the approved and acceptable range of lots which are being used. Control samples are handled in the same manner as patient samples. New shipments and/or lots of reagents will be sequestered prior to quality control testing. The results of controls will be verified for acceptability before reporting patient results and recorded. Once reagents have passed quality control, a green sticker, stating the reagent is ready to use will be added to the reagent.

6. Outdated reagents or quality control materials are not to be used.

7. If controlled temperatures are critical for a procedure, the temperature of a designated incubator, etc., should be checked prior to beginning testing or monitored by automated recording for any variances. The temperature must lie within the approved range or the patient results will not be reported. Records will be monitored daily of each temperature controlled space or equipment. All equipment that have ranges exceeding limits will be taken off line and followed up by the facilities or biomed departments for repair. Document all repairs performed on equipment in the Microbiology Lab.

8. All reagents, standards, reference or control containers will be labeled with the name of the contents, concentration, preparation date, expiration date and storage conditions. The date of receipt into the Microbiology department will be recorded on the package or label as appropriate.

The technologist performing the assay is responsible for checking that the materials used are in conformance with the test protocol and accepted procedures for use of reference or QC related materials. Use components of reagent kits only within the same kit, do not use reagents from one kit with components of a second kit. The technologist must also assure that adequate supplies are available for performing the assay by informing the manager when supplies reach a critical low.

9. Variations from acceptable standards for storage of testing materials, condition of equipment used in testing, reactivity of reagents, or other deviation which could affect results should be brought to the attention of the manager as soon as any such variation is detected.

10. Each individual employee is responsible for the correct, proper and timely performance of his or her work. Whenever a variation or deviation from the expected occurs, the technologist must bring the matter to the attention of the manager. Test results will then be analyzed for validity and/or possible corrective action.

11. All techs will become familiar with the list of Critical Values and the appropriate protocol for reporting critical values. In addition, if a significantly abnormal test result is obtained while performing other tests, the abnormal test result should be reported to the physician even when the test has not been ordered by that physician. If in doubt about reporting an abnormal test result which has not been ordered by the physician, a manager or medical director should be consulted.

12. Turn around times are monitored by the LIS and found in Reports. Most tests have a TAT associated with them and will fall to this report. Any tests listed on this report will be followed up by the Microbiology Manager or designated person.

13. All tests fall to an outstanding list when the result is pending. The bench tech is responsible daily for following up on any tests that have not been resulted or need further information to report the result.