THE SECRETARY OF VETERANS AFFAIRS
WASHINGTON

February 24, 2011

The Honorable William E. Reukauf
Associate Special Counsel
U.S. Office of Special Counsel
1730 M Street, NW
Washington, DC 20036-4505

RE: OSC File No. DI-10-1669

Dear Mr. Reukauf:

I am responding to your letter regarding allegations against employees at the Department of Veterans Affairs Medical Center in St. Louis, Missouri. The specific allegations were made by Ms. Tai-Hwa Holtz, a former medical technologist at the medical center from January 20, 2009 to January 15, 2010. Ms. Holtz asserted that the medical center failed to meet its safety and proficiency requirements under the Clinical Laboratory Improvement Act, in that employees misread test results, overlooked positive test results, and failed to report critical results in a timely manner. You asked me to determine if the alleged misconduct constituted a violation of law, rule, or regulation. In addition, you asked me to determine if there was gross mismanagement or a substantial and specific danger to public health at the medical center.

I asked the Under Secretary for Health to review this matter and take any actions deemed necessary under 5 U.S.C. § 1213(d)(5). He, in turn, directed the Office of the Medical Inspector (OMI) to investigate the disclosures and report their findings. The OMI review is contained in the enclosed Final Report and is submitted for your review. The Medical Center will develop an action plan in response to report recommendations; the OMI will monitor the action plan until completion.

Sincerely,

Eric K. Shinseki

Enclosure

OFFICE OF THE MEDICAL INSPECTOR

Final Report to the

Office of Special Counsel

OSC File Number DI-10-1669

Quality of Laboratory Work

Department of Veterans Affairs Medical Center

St. Louis, Missouri

Veterans Health Administration

Washington, DC

Report Date: January 28, 2011

OMI TRIM # 2010-D-1305

Executive Summary

The Under Secretary for Health requested the Office of the Medical Inspector (OMI) investigate a complaint lodged with the Office of Special Counsel (OSC) by a medical technologist, formerly employed at the St. Louis Veterans Affairs (VA) Medical Center, John Cochran Division, St. Louis, Missouri (hereafter, the Medical Center). The complainant was employed in the microbiology section at the Medical Center from January 20, 2009, until her termination on January 15, 2010. She alleged a number of substandard practices and administrative procedures in which microbiology section employees misread test results, overlooked positive test results, and failed to report critical results in a timely manner. The OMI conducted a site visit to the Medical Center on October 13-14, 2010.

Summary of Conclusions

The OMI did not find evidence of any violation of law, rule, or regulation. The OMI did not find evidence of gross mismanagement. In addition, the OMI did not find evidence that employees in the Medical Center microbiology section misread test results or overlooked positive test results. However, the OMI did find that critical blood culture results were not always reported in a timely manner. In addition, the OMI found that stool samples submitted to the microbiology section were not appropriately preserved. Finally, the OMI found several instances in which the microbiology section failed to keep important documents up to date.

Summary of Recommendations

The Medical Center:

1. Must ensure blood cultures are processed when the blood culture analyzer indicates a potentially positive result and must ensure that the clinical staff is notified immediately of the results.

2. Should ensure that the microbiology section conducts competency testing on its employees and documents the results annually.

3. Should ensure that the microbiology section updates its procedure manual and uses a systematic process for reviewing, revising, and maintaining it in the future, in accordance with College of American Pathologists (CAP) guidelines.

4. Should ensure that the references cited in the procedure manual for testing *Gardnerella vaginalis* are current.

5. Should track the rate of contaminated urine cultures as reported by the microbiology section for a period of at least 6 months and take appropriate action based on the outcome of this evaluation.

6. Should:

    a. Ensure that stool samples (including those for ova and parasites) are transported in an appropriate preservative prior to delivery to the microbiology section,

    b. Ensure that the collection date and time of all stool samples is documented,

c. Monitor for 6 months the implementation of the above two recommendations ensuring compliance.

7. Should ensure that the procedure manual includes instructions on identification and further work-up of diptheroids.

8. Should ensure that reference books being used in the microbiology section are updated and that obsolete or unused references are removed.

9. Should ensure that the microbiology section is consistent in their documentation, adding employee initials, time, and date whenever hand-written changes are made.

Final Report

I. Summary of Allegations

The Under Secretary for Health requested the Office of the Medical Inspector (OMI) investigate a complaint lodged with the Office of Special Counsel (OSC) by a medical technologist, formerly employed at the St. Louis Veterans Affairs (VA) Medical Center, John Cochran Division, St. Louis, Missouri (hereafter, the Medical Center). The complainant was employed in the microbiology section at the Medical Center from January 20, 2009, until her termination on January 15, 2010. She alleged a number of substandard practices and administrative procedures in which microbiology section employees misread test results, overlooked positive test results, and failed to report critical results in a timely manner.

II. Facility Profile

The Medical Center is a full-service health care facility providing inpatient and ambulatory care in medicine, surgery, psychiatry, neurology, and rehabilitation, as well as in over 65 subspecialty areas. It is a two-division facility that serves Veterans and their families in east central Missouri and southwestern Illinois. The John Cochran Division is located in midtown St. Louis and has all of the Medical Center's operative surgical capabilities, the ambulatory care unit, inpatient medical and surgical units, intensive care units, outpatient psychiatry clinics, and the clinical laboratory.

The Pathology & Laboratory Medicine Service (PLMS) consists of several sections, including the chemistry, hematology, and microbiology sections. The microbiology section conducts various tests to isolate and identify microorganisms in body fluids and tissue samples. The PLMS provides 24-hour coverage of many, but not all, laboratory services. The PLMS also has a central receiving section which performs blood and urine collection from patients who come to the laboratory, receives specimen samples from inpatient and outpatient areas, and distributes these samples to the appropriate laboratory section for testing.

The PLMS laboratory was fully accredited by the College of American Pathologists (CAP) during the complainant's employment there and continues to hold full accreditation through February 28, 2011.[1] In January 2010, however, the CAP recommended the Medical Center to cease testing for acid-fast bacilli, the microorganism that causes tuberculosis, and for fungi, because on a focused review of the microbiology section, the CAP inspector felt their staffing was not adequate. The Medical Center agreed to stop this in-house testing and to send these tests out a reference laboratory. In line with the inspector's recommendation, the Medical Center began the recruitment process for an additional 3.4 full-time equivalent employees in February 2010. The OMI was informed that two of these employees have been hired and a third will begin work shortly.

[1] The College of American Pathologists is the professional certifying body for clinical laboratories.

III. Conduct of the Investigation

On October 8, the OMI held a telephone conference with the complainant in which she made additional allegations. A team consisting of the Medical Inspector (a physician), the Deputy Medical Inspector for National Quality Assessments (a physician), a Clinical Program Manager (a registered nurse), and a medical technologist (employed as the microbiology section supervisor at another full-service VA medical center), conducted a site visit on October 13-14, 2010. The team toured the PLMS, interviewed individuals, reviewed policies, procedures, microbiology reports, and laboratory results. A full list of the documents reviewed by the team is in the Appendix. The team held entrance and exit conferences with the Medical Center leadership.

During the site visit, the OMI team interviewed, either in person or via telephone, the following individuals:

1. the Acting Chief, PLMS,
2. the supervisor, microbiology section,
3. a staff pathologist with technical oversight for the microbiology section,
4. the Associate Director for Patient/Nursing Services,
5. a chemistry technologist who also served as co-microbiology section supervisor,
6. an attending physician in the Intensive Care Unit,
7. two attending gastroenterologists,
8. the Chief, Infectious Disease Service,
9. the Infection Control Nurse,
10. a medical technologist in the microbiology section,
11. a medical technician in the microbiology section for the weekday evening shifts, and
12. an employee in the central receiving section.

The OMI ***did substantiate*** allegations when the facts and findings supported that the alleged events or actions took place. The OMI ***did not substantiate*** allegations when the facts showed that the allegations were unfounded. The OMI ***could not substantiate*** allegations when there was no conclusive evidence to either sustain or refute the allegations.

IV. Summary of Evidence Obtained from the Investigation

A. Allegations in the letter from the OSC to the Secretary of Veterans Affairs

Allegation #1

There is no microbiology section coverage for the night shift during the week and no coverage for evening and night shifts on the week-end. As a result, positive blood cultures can go unprocessed and the results unreported for up to 16 hours.

Findings

A blood culture is a laboratory test used to determine the presence of microorganisms in a sample taken from the patient's normally sterile blood stream. Blood cultures that are positive for microorganisms may indicate a blood stream infection which is a serious

condition needing immediate medical attention. Modern blood culture analyzers are automated and detect potentially positive blood culture results at any time of the day without technician involvement. Initial confirmation of these potentially positive results requires a technician to sample, stain, and microscopically review a sample from the blood culture analyzer. This initial conformation procedure usually takes 20 to 30 minutes and, if positive, requires immediate notification of the clinical staff.

Review of the microbiology section staff schedules showed that the microbiology section was staffed only from 8:00 a.m. to 1:00 a.m. Monday through Friday and from 8:00 a.m. until 4:30 p.m. on weekends and holidays. Further, no provision for initial confirmation of potentially positive blood culture results by the off-hours laboratory staff was in place. So, during the off-hour periods, potentially positive blood cultures were not further processed at the time the blood culture analyzer initially detected them, nor were they reported to the clinical providers. The attending physicians who care for potentially infected patients did not know that the reporting of initial blood culture growth was being delayed until the next morning; however, they noted that they usually treat such patients with antibiotics in anticipation of positive blood culture results, halting the antibiotics if the blood culture results were negative and if the patient's clinical response warranted it.

VA's National Director, Pathology & Laboratory Medicine Service and the Associate Chief Consultant for Diagnostic Services agree that immediate processing and reporting of initially positive blood culture results to the clinical staff is the community standard and is mandatory.

Conclusion

The OMI substantiates the complainant's allegation that the microbiology section is not covered during the night shift on weekdays and during evening and night shifts during the weekend and on holidays. Further, we substantiate the allegation that there is in some instances a delay in processing potentially positive blood culture findings and in immediate notification of these positive findings to the clinical staff.

Recommendation

The Medical Center must ensure blood cultures are processed when the blood culture analyzer indicates a potentially positive result and must ensure that the clinical staff is notified immediately of the results.

Allegation #2

The microbiology section did not conduct any monitoring or checking of employee proficiency during the complainant's tenure January 2009-2010.

Findings

The microbiology section follows the Medical Center policy regarding maintaining and monitoring employee competencies. The section keeps competency folders on each employee.

After the CAP inspection in 2009, the section supervisor restructured the template used to document employee competencies and wrote specific assessment of competencies for the staff. However, she did not record her employees' competencies until 2010. These assessments must be conducted and recorded on a yearly basis, according to CAP standards. In 2010, the facility underwent a focused CAP inspection of the microbiology section staff's proficiency-testing program and the CAP inspector found the competencies to be appropriate. The OMI team reviewed the microbiology section staff competency folders and also found them to be appropriate.

Conclusion

The OMI substantiates that the microbiology section was not in compliance with the requirement to record the competency testing of their employees in 2009. However, a focused CAP inspection conducted in 2010 found the competency program including documentation of the results of competency testing to be appropriate. The OMI team also found the microbiology section competency program including documentation to be appropriate.

Recommendation

The Medical Center should ensure that the microbiology section conducts competency testing on its employees and documents the results annually.

Allegation #3

The microbiology section lacks continuing education and remedial training for its staff.

Findings

Continuing education is defined as educational activities related to an individual's original field of certification that is above and beyond basic education and training. Remedial training is training intended to correct or improve deficient skills in a specific subject.

The OMI team reviewed the Medical Center's *Travel and Educational Details Policy*, dated October 15, 2009, which covers all employees, including those in the microbiology section. This policy delineates which continuing education activities qualify for support and funding: they are those that improve employee performance of current duties, maintain specialized proficiencies, keep employees abreast of the state-of-the-art, and provide them with the skills, knowledge, and abilities necessary to accommodate to changing policies and technology. It also states that employees having less than 1 year of current, continuous service in the government will not normally be approved for funding by the Medical Center.

Some employees who qualify for funding told OMI they have attended continuing education activities.

The OMI found that remedial training is rarely necessary in the microbiology section. Our review of employee competency folders from January 2009 to the present showed that remedial training was necessary in only one case. In that case, an employee received additional training in reading bacterial sensitivity to antibiotics. The microbiology section supervisor indicated there has not been the need for any of her staff to receive remedial training this year.

Conclusion

The OMI team did not substantiate that there was a lack of opportunity for continued education. By Medical Center policy, however, the complainant would not normally have been considered for funded continuing education opportunities because she had less than 1 year of service in the Medical Center. Had she met the time-in-service requirement, the Medical Center's education policy clearly outlines the steps to follow for requesting continued education. The OMI team does not substantiate the allegation that there is a lack of remedial education. Remedial training was required and completed on one employee during the complainant's tenure.

Recommendation

The OMI makes no recommendations regarding this allegation.

Allegation #4

The microbiology section lacks a procedure manual.

Findings

A procedure manual generally outlines what studies the laboratory does and how these studies are to be performed. The OMI found that the microbiology section has a procedure manual and found that employees sign to certify that they have read the manual. We found that the complainant had initialed the procedure manual in 2009. However, we also found that the procedure manual was not consistently updated on an annual basis, as required by CAP. Many of the revisions made were hand-written in ink and bore unclear dates and initials of the person making the change. Also, some of the cited references were outdated. Interviews with the Acting Chief, PLMS and the supervisor of the microbiology section indicated that they were in the process of revising their procedure manual and acknowledged needing a document control system to ensure timely revisions.

Conclusion

The OMI did not substantiate that the microbiology section lacked a procedure manual. The section has a procedure manual and the complainant initialed it; however, the procedure manual needs to be updated.

Recommendation

The Medical Center should ensure that the microbiology section updates its procedure manual and uses a systematic process for reviewing, revising, and maintaining it in the future in accordance with CAP guidelines.

Allegation #5

The microbiology section does not test for *Gardnerella vaginalis*.

Findings

Gardnerella vaginalis is a bacterial species found in the genital tracts of healthy adults of both sexes. In particular, it may be found in the normal vaginal flora. However, in circumstances in which there is an excess growth of *Gardnerella vaginalis*, infection may occur. *Gardnerella vaginalis* has also been reported as a pathogen in males.

The procedure manual describes the technique for identifying *Gardnerella vaginalis,* although the cited references are outdated. Further, the microbiology section provided the OMI team with an *ad hoc* query of the Medical Center's electronic medical record results for *Gardnerella vaginalis* in urine and on cervical isolates between January 1, 2009, and January 22, 2010. This query yielded more than 20 positive culture results.

Conclusion

The OMI did not substantiate a lack of testing for *Gardnerella vaginalis*. Again, the references cited in the procedure manual are outdated.

Recommendation

The Medical Center should ensure that the references cited in the procedure manual for testing *Gardnerella vaginalis* are current.

Allegation # 6

The microbiology section lacks an approved procedure to test for extended-spectrum beta lactamase (ESBL).

Findings

ESBL is an enzyme produced by some bacteria that helps confer resistance to common antibiotics. The presence of ESBL-producing bacteria can be completely harmless in healthy individuals, but may cause serious infection in individuals with poorly functioning immune systems. Testing for ESBL should be performed only on bacteria known to produce it. Testing for ESBL is an integral part of antimicrobial susceptibility testing for bacteria that produce it, so it is not routinely considered a separate procedure.

The OMI reviewed the procedure manual entry dealing with testing for ESBL, last revised in February 2009. This procedure outlines the steps in specimen testing and in verification of the presence of an ESBL. Specifically, the section has been using the Vitek®2 susceptibility card system that has an ESBL confirmatory test included since December 2008. This system provides rapid confirmatory testing of ESBL strains of bacteria.

Conclusion

The OMI team did not substantiate that the microbiology section lacked a written procedure for conducting ESBL confirmatory testing.

Recommendation

The OMI makes no recommendations regarding this allegation.

Allegation # 7

Urine culture contamination rates are high, due to a lack of additional identification and susceptibility testing.

Findings

A urine culture identifies microorganisms present in the urine. In most instances, microorganisms isolated by urine culture reflect infection of the urinary tract, which includes the kidneys, bladder, and urethra. Microorganisms isolated in urine cultures, in the absence of urinary tract infection, may be due to contamination by microorganisms on the skin. Contamination of urine collected for culture can occur if the urine is improperly collected or if it is allowed to stand unrefrigerated prior to processing.

The microbiology section does not track urine culture contamination rates. In interviews with the OMI team, the microbiology section supervisor, the Chief, Infectious Disease Service who is also the Chairman, Infection Control Committee, and the Infection Control Nurse could not cite the Medical Center's rate but none thought the urine culture contamination rate was high.

Neither the CAP nor VA requires monitoring of urine culture contamination rates. The OMI team reviewed the urine culture worksheets dating back to 2007, and determined that additional identification and susceptibility testing were conducted when required.

Conclusion

Because the Medical Center does not track its urine culture contamination rate, the OMI could not substantiate that the facility has a high rate. Tracking urine culture contamination rates it is not a standard procedure for microbiology laboratories. However, the microbiology section does appropriate additional testing on potentially positive urine cultures when required.

Recommendation

The Medical Center should track the rate of contaminated urine cultures for a period of at least 6 months and take appropriate action based on the outcome of this evaluation.

Allegation #8

Raw stool samples were inappropriately transported from the ward or clinic areas to the microbiology section by not being placed in Cary-Blair medium within 1 hour of collection.

Findings

Stool is often cultured to identify microorganisms that may cause gastrointestinal symptoms, such as diarrhea. Some pathogenic microorganisms that may be recovered from stool samples do not survive to be identified by stool culture unless the sample has been processed quickly or placed into a preservative. Stool submitted for culture that is not in an appropriate preservative must be processed within 2 hours of collection to ensure accurate identification of pathogenic microorganisms. However, if the stool sample is submitted for culture in a preservative, the specimen may be refrigerated and processed for culturing for up to 24 hours. Failure to adequately preserve a stool sample prior to culture may result in a stool culture that is falsely negative for pathogenic bacteria. The Cary-Blair medium is commonly used to preserve sensitive microorganisms in stool samples during transport and storage.

During interviews with the OMI team, the Acting Chief, PMLS, the microbiology section supervisor, the central receiving section technician, and a medical technologist confirmed that the stool samples are often received in a sterile specimen cup without preservatives. In addition, these interviewees indicate that many stool samples arrive at the central receiving section without documentation of the date and time of specimen collection, making it impossible to determine whether culture of the sample can reliably exclude the presence of pathogenic microorganisms.

According to the microbiology section staff, the preservatives have been made available to the nursing staff on the inpatient units and clinics, but the samples have still been arriving in an unpreserved state and without notation of the date and time of collection. The Associate Director for Patient/Nursing Services agreed the nursing units needed to address the concerns about documentation of the date and time of sample collection and about the use of the preservative.

Conclusion

The OMI substantiated that stool samples often are transported to the microbiology section without an appropriate preservative and without documentation of the time and date of collection.

Recommendations

The Medical Center should ensure that stool samples are transported in an appropriate preservative prior to delivery to the microbiology section. Also, the Medical Center should ensure that the collection date and time of all stool samples is documented. Finally, the Medical Center should monitor the implementation of these recommendations ensuring compliance.

Allegation #9

During the complainant's employment tenure, the microbiology section never identified *Campylobacter*. The Infection Control Nurse was advised of this, but did not act. Subsequently, Cary-Blair transport vials were ordered, but never delivered.

Findings

Campylobacter jejuni, which can be identified by stool culture, is a microorganism that causes gastroenteritis, which can include fever, abdominal pain, and diarrhea. *Campylobacter jejuni* remains viable in unpreserved stool samples for up to 72 hours.

The records presented to the OMI team indicate that no cultures identified *Campylobacter jejuni* between January 2009 and January 2010. The procedure log books and quality control records indicate that stool samples were being tested for *Campylobacter jejuni*. Even in the absence of preservative, identification of *Campylobacter jejuni* in stool infected with this microorganism is expected.

In its *Communicable Disease Surveillance Report 2008*, the Centers for Diseases Control and Prevention (CDC) note Missouri has fewer cases of *Campylobacter jejuni* gastroenteritis than is to be expected for its population. The CDC attributed the low incidence of *Campylobacter jejuni* infection to Missouri's excellent food safety programs and regulations, although the exact reason for Missouri's low incidence of *Campylobacter jejuni* infections is not known.

The Infection Control Nurse denied being approached by the complainant or any other staff member about the lack of *Campylobacter* identification.

Cary-Blair transport media are now available on the wards and in the clinics. The OMI was unable to determine exactly when they were placed there.

Conclusion

The OMI substantiated that the microbiology section did not isolate *Campylobacter jejuni* during the complainant's employment tenure; however, OMI did not substantiate that the absence of positive *Campylobacter jejuni* stool cultures was related to incorrect testing or to the failure to use stool specimen preservative (e.g., the Cary-Blair medium). The OMI did not substantiate that the Infection Control Nurse was told about the lack of isolation of *Campylobacter*. The OMI could not substantiate when the transport media were delivered to the clinical areas.

Recommendation

The OMI makes no recommendations regarding this allegation.

Allegation #10

Throughout the complainant's employment tenure, there were no positive results for ova and parasites in stool samples. These samples were transported to the reference lab without being appropriately placed in proper chemical transport media.

Findings

Testing for ova and parasites in stool samples identifies specific intestinal infections due to parasitic microorganisms which may appear in the stool as mature organisms (parasites) or as eggs (ova). Parasitic intestinal infection may be asymptomatic or cause symptoms or signs including diarrhea, blood in the stool, and weight loss. In order to ensure identification of all parasites in a stool sample, the sample must be processed within 2 hours of collection, refrigerated, or immersed in a preservative.

The OMI team found that during the complainant's employment tenure, the microbiology section sent stool samples to the reference laboratory rather than process them in the microbiology section. We also found one positive laboratory report for ova and parasites dated October 18, 2009, as well as several negative laboratory reports for stool ova and parasites. The reference laboratory requires that stool samples to be analyzed for ova and parasites be immersed in preservative or the sample may be rejected. The central receiving section employee indicated that all stool samples sent to the reference laboratory were packaged according to the reference laboratory instructions. Since the complainant has left employment at the Medical Center, the reference laboratory has reported positive stool samples for ova and parasites, on February 2 and 26, April 9, May 27, and June 15, 2010.

Conclusion

Although one positive stool sample for ova and parasites was reported during the complainant's employment tenure and the central receiving section employee relates compliance with the reference laboratory requirement for specimen packaging, the increase in the number of positive stool samples for ova and parasites immediately after the complainant left Medical Center employment suggests a possible problem with stool preservation and packaging before January 2010. However, the increase in the number of positive stool samples for ova and parasites since January 2010 also suggests possible problems with packaging and transport to the reference laboratory have been resolved.

Recommendation

The Medical Center should monitor stool samples to be examined for ova and parasites which are presented to the central receiving section for 6 months to ensure the samples arrive in an appropriate preservative. (In the Summary of Recommendations, this recommendation is combined with the recommendation for allegation #8.)

B. Additional allegations made in a telephone interview with OMI on October 8, 2010

Allegation #11

Diphtheroid bacteria are reported as normal flora with no further work up.

Findings

Diptheroid is the name given to microorganisms of the *Corynebacterium* group that usually do not cause disease. Diptheroids are found widely in nature including on human skin. Often, isolation of *Corneybacteria* in blood samples reflects contamination of the sample by these diptheroids from the skin. However, further microbiologic work up and evaluation may be required by the clinical laboratory to confirm that a specific diptheroid isolate is a contaminate and not a disease-causing organism.

The OMI reviewed the procedure manual and found that it lacked clear instruction regarding the circumstances under which diptheroid isolates are worked up to confirm the isolate as a contaminate. Also, the procedure manual did not outline the steps to follow when further work up was required. The microbiology section supervisor said that when diphtheroids were isolated consistently on blood culture of the same patient, further work up is always conducted.

Conclusion

Although the microbiology section does not have clear guidance on the identification and further work up of diptheroid isolates, the OMI team found no evidence that *Corynebacteria* causing disease were reported out as diptheroid contaminates. The OMI did not substantiate that diphtheroid findings were not worked up further when warranted. The team found that the procedure manual lacked specific instructions on when to conduct additional work up.

Recommendation

The Medical Center should ensure that the procedure manual include instructions on identification and appropriate work up of diptheroids.

Allegation #12

Mycology and mycobacteria testing were discontinued even though the microbiology section owns the equipment to test for these microorganisms.

Findings

As noted above, testing for fungi (mycology) and for mycobacteria was suspended in January 2010 based on a management decision and agreement with the CAP that the staffing for the microbiology section was inadequate. The microbiology section supervisor said that samples that were to be tested for fungi or mycobacteria were sent to the reference laboratory as soon as the testing was suspended, without any gap in service. The OMI team reviewed the mycology culture reports from the reference laboratory and validated that testing for these microorganisms was uninterrupted.

Conclusion

Mycology and mycobacteria testing was discontinued based on a management decision and agreement with the CAP that staffing was insufficient. However, there was no gap in service because samples were sent to the reference laboratory as soon as the testing at the Medical Center was suspended.

Recommendation

The OMI makes no recommendations regarding this allegation.

Allegation #13

There is no opportunity for "on-the-job training."

Findings

"On-the-job training" is un-accredited, informal, and unstructured training of an employee to perform a task outside of his or her position description, often undertaken by supervisors based on need.

In its interviews with Medical Center employees, the OMI team found that continuing education and remedial training opportunities exist. The OMI found no evidence of "on-the-job training" in the microbiology section, since all employees in that section are trained to be able to perform all the relevant microbiology tasks at the time they are hired.

Conclusion

The OMI team found no evidence of an "on-the-job training" type program in the microbiology section; however, the microbiology section has no requirement for such a program.

Recommendation

The OMI makes no recommendation regarding this allegation.

Allegation #14

The API book used to identify organisms is outdated (1970) and updates are not purchased.

Findings

Analytical Profile Index (API) is a commercially available system that helps identify certain microorganisms. The system requires inoculation of a sample into multiple compartment system where reactions occur. The microorganism can be identified based on the specific compartment reactions. Previously, the specific compartment reactions had to be compared to known compartment reactions in the API reference book. With the internet, the on-line application called apiWeb™ has replaced the reference book. The microbiology section supervisor and employees all said they were familiar with and used apiWed™.

Conclusion

Although the OMI team found the outdated API book in the microbiology section, the book was not being used to identify microorganisms.

Recommendation

The Medical Center should ensure that reference books being used in the microbiology section are updated and that obsolete or unused references are removed.

Allegation #15

The quality control books are outdated.

Findings

Quality control books are records that a laboratory keeps which document the integrity of the reagents that are used in clinical testing. Carefully documented quality control books allow a clinical laboratory to attest to the accuracy of test results long after the test has been completed. For example, the CAP Microbiology Checklist requires that each shipment of purchased media be examined for breakage, contamination, appearance, and evidence of freezing or overheating. It further requires that the results of this inspection be logged in the quality control books.

The microbiology section quality control books were reviewed by the OMI team. We found that the books are present and kept up to date but found the documentation in them to be inconsistent. For example, in one, the word "sterility" was hand-written onto a standard quality control template after the quality control test was run. This correction was not initialed or dated, as required by CAP.

Conclusion

The OMI concluded the microbiology section had quality control books and that they were kept up to date. However, some documentation is not consistent and when hand-written changes are made to templates, they are not initialed, timed, and dated by the employee making the changes.

Recommendation

The Medical Center should ensure that the microbiology section is consistent in their documentation, adding employee initials, time, and date whenever hand-written changes are made.

Allegation #16

Microbiology section employees misread Gram stains.

Findings

The Gram stain is one of the most common initial clinical laboratory tests conducted on patient samples to identify the presence of microorganisms and to give an initial indication of the type of microorganism present. This test is one of the oldest tests in the microbiology laboratory and all microbiology laboratory employees are expected to be able to perform the stain and interpret the results.

The microbiology section's on-going competency monitoring program requires the employee to interpret an unknown Gram stain and compare their interpretation with the known result. The evaluation tool includes the number, identification and date of the slide, the result of the evaluation, the employee's initials, and the supervisor's comments. The OMI's review of the employee competency folders showed that all employees performed this competency satisfactorily. The medical staff we interviewed did not know of an instance in which a Gram stain was misinterpreted.

Conclusion

The OMI did not substantiate that Gram stains were being misinterpreted.

Recommendation

The OMI makes no recommendation regarding this allegation.

Allegation #17

Microbiology reports usually take several days to complete. If you only verify the final and not the preliminary reports, mistakes cannot be detected in a timely manner. No one actually checks the microbiology report on the computer screen against the culture reports recorded in the work book.

Findings

The microbiology section identifies microorganisms in a submitted sample by applying a portion of the sample to several Petri dishes filled with different types of growth media. Each of the different media supports the growth of a specific microorganism or group of microorganisms. After 24 hours, a preliminary identification of a growing colony of microorganisms is made by observing the morphology of the colony, staining and microscopically examining a portion of the colony, noting on which media the colonies are growing, and applying microorganism-specific biochemical markers to a colony. The microbiology technologist records the preliminary identification in a laboratory workbook and enters the preliminary report in the electronic medical record. Because some microorganisms grow more slowly than others, the Petri dish samples may be held for up to 7 days to assure all microorganisms in the submitted sample are identified before the report is finalized. Prior to report finalization, updates to the initial preliminary report may be added if more microorganisms are identified.

The microbiology section supervisor validates the preliminary report in the electronic medical record by comparing the report with the entry in the workbook. Information provided to the OMI team demonstrated she validates roughly 5 to 10 per cent of samples submitted for culture.

Once the Petri dish samples have been incubated for the prescribed length of time, and all microorganisms in the submitted sample are identified, the final report is entered into the electronic medical record. The microbiology section supervisor compares a sample of final reports with the corresponding preliminary reports. In submitted samples with slow-growing microorganisms, up to a week may elapse between the preliminary and final reports.

Conclusion

Although some microbiology reports take several days to finalize, this time is needed to ensure all microorganisms in the submitted sample are identified and reported. The preliminary identification and report is usually available in 24 hours and is updated if additional microorganisms are identified. The microbiology section supervisor validates a sample of preliminary reports in the electronic medical record against the laboratory workbook, detecting transcription errors. Validation of preliminary reports against final report occurs later because the final reports are often not issued until days after sample submission.

The OMI team did not substantiate that the microbiology section reports final results inappropriately late. Also, we did not substantiate the allegation that mistakes are not detected in a timely manner because preliminary report validation between the electronic

medical record and the laboratory workbook and between the preliminary and final reports does occur. Finally, the OMI team did not substantiate the allegation that no one validates the preliminary report in the electronic medical record against the laboratory workbook.

Recommendation

The OMI makes no recommendation regarding this allegation.

Summary of Conclusions

The OMI did not find evidence of any violation of law, rule, or regulation. The OMI did not find evidence of gross mismanagement. In addition, the OMI did not find evidence that employees in the Medical Center microbiology section misread test results or overlooked positive test results. However, the OMI did find that critical blood culture results were not always reported in a timely manner. In addition, the OMI found that stool samples submitted to the microbiology section were not appropriately preserved. Finally, the OMI found several instances in which the microbiology section failed to keep important documents up to date.

Summary of Recommendations

The Medical Center:

1. Must ensure blood cultures are processed when the blood culture analyzer indicates a potentially positive result and must ensure that the clinical staff is notified immediately of the results.

2. Should ensure that the microbiology section conducts competency testing on its employees and documents the results annually.

3. Should ensure that the microbiology section updates its procedure manual and uses a systematic process for reviewing, revising, and maintaining it in the future, in accordance with CAP guidelines.

4. Should ensure that the references cited in the procedure manual for testing *Gardnerella vaginalis* are current. Should track the rate of contaminated urine cultures as reported by the micr*obiology section for* a period of at least 6 months and take appropriate action based on the outcome of this evaluation.

5. Should:

    a. Ensure that stool samples (including those for ova and parasites) are transported in an appropriate preservative prior to delivery to the microbiology section,

    b. Ensure that the collection date and time of all stool samples is documented,

    c. Monitor for 6 months the implementation of the above two recommendations ensuring compliance.

7. Should ensure that the procedure manual includes instructions on identification and further work-up of diptheroids.

8. Should ensure that reference books being used in the microbiology section are updated and that obsolete or unused references are removed.

9. Should ensure that the microbiology section is consistent in their documentation, adding employee initials, time, and date whenever hand-written changes are made.

Appendix

Documents Reviewed

Pathology and Laboratory Medicine Service (PMLS) Procedures: VHA Handbook 1106.01, October 6, 2008.

Ad hoc query of the Medical Center's reports for *Gardenella Vaginalis* for January 2009-2010.

Ad hoc query reports for diphtheroid in sterile body site for January 2009-2010.

Copy of *Campylobacter* media Quality Control records dated January 2009-2010.

Ad hoc reports of testing for Ova & Parasites (results) for January 2009-2010.

Procedure manual for the PMLS with acknowledgement sheets bearing the signatures of all staff members in the PLMS who have read the manual.

Mycology Reports

A copy of the License to use the apiWeb™ electronic system from BioMerieux, Inc.

Microbiology staff competency folders

CAP Laboratory Accreditation Reports 2009 and 2010

American Society for Clinical Laboratory Science website http://www.ascls.org/

Clinical Microbiology Procedures Handbook, 3rd ed, Garcia et al, American Society of Microbiologists Press, 2010

Manual of Clinical Microbiology, 9th ed, Murray et al, American Society of Microbiologists Press, 2007