

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0032885	(X3) Date Survey Completed 03/06/2018
Name of Provider or Supplier Uh Portage Medical Center	Street Address, City, State 6847 N Chestnut Street, Ravenna, OH	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record reviews and interviews with the Laboratory Director and Testing Personnel (TP), the Laboratory Director failed to sign the proficiency testing (PT) provider's attestation statement attesting to the routine integration of PT samples into the patient workload using the laboratory's routine methods. Findings Include: 1. Review of 5 out of 5 of the laboratory's 2016 and 2017 College of American Pathologists (CAP) Chemistry PT records, provided on the date of the inspection, did not find any signature of the Laboratory Director attesting to the routine integration of PT samples into the patient workload using the laboratory's routine methods; TS#10 signed the PT provider's attestation statements as the Laboratory Director. 2. The Surveyor requested the Laboratory Director's written delegation letter, delegating the Laboratory Director's PT attestation responsibilities to TS#10. The Laboratory Director confirmed a letter of delegation was not available and was unable to provide the requested documentation on the date of the inspection. The interviews occurred on 03/06/2018 at 8:37 AM.</p>
D2039	<p>MYCOLOGY CFR(s): 493.827(b)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2)</p>

The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on record review and an interview with Technical Supervisor (TS) #9, the laboratory failed to participate in the third Mycology proficiency testing (PT) event of 2017 for 4 out of the 5 PT samples provided. Findings Include: 1. Review of three out of three of the laboratory's 2017 College of American Pathologists (CAP) Mycology PT records, provided on the dates of the inspection, revealed an overall Mycology PT event score of 100% for the third testing event of 2017 (F-C). 2. Further review of the evaluation summary for five out of the five samples provided to the laboratory for the 2017 CAP F-C PT event revealed the results for the Fungal Identification testing for samples F-14, F-15, F-16 and F-17, were not tested and reported. 3. The Surveyor requested the laboratory's 2017 documentation of compliance for PT participation for the regulated mycology identification testing that included five testing challenges in each of three testing events in 2017 from TS#9. TS#9 stated that the laboratory was unaware of the PT participation requirements for regulated analytes, was unaware that further testing of four more PT samples were required for the third testing event in 2017 and confirmed that the laboratory did not conduct any other mycology identification PT activities for the third testing event in 2017. The interview occurred on 03/06/2018 at 10:30 AM.

D5213

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on record review and interviews with Technical Supervisors (TS) #2 and TS#9, the laboratory failed to verify the accuracy of analytes not evaluated or scored by the College of American Pathologists (CAP) proficiency testing (PT) provider. Findings Include: 1. Review of 12 out of 47 of the laboratory's 2017 CAP Bacteriology, Mycobacteriology, Mycology, Parasitology, Virology and Cytology PT events, provided on the dates of the inspection, revealed the laboratory tested and reported results on educational challenge samples. 2. Further review of 12 out of 12 of the laboratory's 2017 CAP PT events with educational challenge results or lack of participant or referee consensus did not find any self evaluation documentation of acceptability as listed below: Methicillin Susceptible Staphylococcus Aureus MRS5-A (5 samples) MRS5-B (5 samples) MRS5-C (5 samples) Vaginitis Screen, Nugent Scoring VS2-A (3 samples) VS2-B (3 samples) Bacteriology Minimal Inhibitory Concentration (MIC) D-A (2 samples; D-01, D-05) D-B (1 sample; D-12) Gram Stain D5-A (5 samples) D5-B (5 samples) D5-C (5 samples) Trichomonas Vaginalis Molecular TVAG-B Bordetella Pertussis BOR-B 3. TS#2 and TS#9 stated they were unaware of the requirement to verify and document the accuracy of analytes not

evaluated or scored by the PT provider against the participant summary and confirmed the laboratory did not document any self evaluation activities when the results were not graded. The interviews occurred on 03/06/2018 at 10:30 AM and 12:15 PM.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:
Based on direct observation and an interview with Testing Personnel (TP) #36, the laboratory failed to label the immunohematology saline squeeze bottles secondary containers with the correct storage conditions, lot numbers and expiration dates. Findings Include: 1. Direct observation of the immunohematology laboratory, on 3/6/18 at 9:47 am, found two out of two squeeze bottles of saline labeled as "Saline, change daily." 2. An interview with TP #36, on 3/6/18 at 9:47 am, confirmed that the laboratory did not document daily changing of the immunohematology saline squeeze bottles or the lot number, expiration date and storage conditions on the secondary containers, as required.

D6108

LABORATORY TECHNICAL SUPERVISOR
CFR(s): 493.1447

The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

This CONDITION is not met as evidenced by:
Based on record review and an interview with the Laboratory Manager (LM), the laboratory failed to ensure that Technical Supervisors (TS) met the minimum qualification requirements of 493.1449(c)(d)(e)(f)(g)(h)(i)(j)(k) and provided technical supervision in accordance with 493.1451 of this subpart. Findings Include: 1. The laboratory failed to ensure that Technical Supervisors (TS) #1, TS#2 and TS#9 met the minimum TS qualification requirements for the high complexity testing procedures performed in the subspecialty of Cytology; 493.1449(k). (Refer to D6111, Item 1) 2. The laboratory failed to ensure that Technical Supervisors (TS) #4 and TS#9 met the minimum TS qualification requirements for the high complexity testing procedures performed in the specialties of Immunology; 493.1449(h), Chemistry; 493.1449(i) and Hematology; 493.1449(j). (Refer to D6111, Item 2) 3. The laboratory failed to ensure that Technical Supervisor (TS) #9 met the minimum TS qualification requirements for the high complexity testing procedures performed in the subspecialties of Bacteriology; 493.1449(c), Mycobacteriology; 493.1449(d), Mycology; 493.1449(e), Parasitology; 492.1449(f) and Virology; 493.1449(g). (Refer to D6111, Item 3) 4. The Technical Supervisor (TS) failed to evaluate and document the performance of TP#3 who was responsible for high complexity Microbiology and Immunology testing procedures at least semiannually during the first year the individual tested patient specimens. (Refer to D6127) 5. The Technical Supervisor

(TS) failed to evaluate and document the performance of Testing Personnel (TP) who were responsible for high complexity Microbiology and Immunology testing procedures at least annually after the first year the individuals tested patient specimens. (Refer to D6128, Item 1) 6. The Technical Supervisor (TS) failed to ensure policies and procedures were followed for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing assuring they are competent and maintain their competency to process specimens, perform test procedures, and report test results promptly and proficiently. (Refer to D6128, Item 2) 7. The Technical Supervisor failed to ensure policies and procedures were followed for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing assuring they are competent and maintain their competency to process specimens, perform test procedures, and report test results promptly and proficiently in the specialty of Hematology. (Refer to D6128, Item 3) 8. The Technical Supervisor failed to ensure policies and procedures were followed for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing assuring they are competent and maintain their competency to process specimens, perform test procedures, and report test results promptly and proficiently in the specialty of Immunohematology. (Refer to D6128, Item 4)

D6111

TECHNICAL SUPERVISOR QUALIFICATIONS

CFR(s): 493.1449

(a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the

subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must-- (e)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (e)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (e)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience

in high complexity testing within the subspecialty of mycology; or (e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (e)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology. (f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must-- (f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (f)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (g)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience

in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must-- (h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (h)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (i)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (i)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American

Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (j)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)

(3) For tests in ophthalmic pathology, meet one of the following requirements: (1)(3)(i) (A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (1)(3)(i)(B) Must meet one of the following requirements: (1)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (1)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (1)(3)(ii) An individual qualified under 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (n)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or

experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (q)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

This STANDARD is not met as evidenced by:

Item 1: Based on record review and an interview with the Laboratory Manager (LM), the laboratory failed to ensure that Technical Supervisors (TS) #1, TS#2 and TS#9 met the minimum TS qualification requirements for the high complexity testing procedures performed in the subspecialty of Cytology; 493.1449(k). Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed and dated by the Laboratory Director on 03/05/2018, revealed five out of 61 individuals listed and certified by the Laboratory Director to fulfill the position and responsibilities of TS for the high complexity Cytology testing procedures performed. 2. Review of the education documentation, provided on and within seven calendar days of the exit date of the inspection, found three out of the five TS's indicated did not meet the minimum education qualifications to fulfill the position and responsibilities of a TS in Cytology

as listed below: a) TS#1 possesses a Bachelor of Science with an American Society of Clinical Pathologists (ASCP) board certification as a "Technologist in Microbiology" and does not meet the minimum education requirements to fulfill the position and responsibilities of a TS in Cytology. b) TS#2 possesses a Bachelor of Arts with an ASCP certification as a cytotechnologist and does not meet the minimum education requirements to fulfill the position and responsibilities of a TS in Cytology. c) TS#9 possesses a Bachelor of Science in Public Health and an Associate of Applied Science in Medical Laboratory Technology and does not meet the minimum education requirements to fulfill the position and responsibilities of a TS in Cytology. 3. The LM confirmed the above mentioned education documentation for TS#1, TS#2 and TS#9 were their highest levels of education achieved. The phone interview occurred on 03/13/2018 at 3:00 PM. Item 2: Based on record review and an interview with the Laboratory Manager (LM), the laboratory failed to ensure that Technical Supervisors (TS) #4 and TS#9 met the minimum TS qualification requirements for the high complexity testing procedures performed in the specialties of Immunology; 493.1449(h), Chemistry; 493.1449(i) and Hematology; 493.1449(j). Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed and dated by the Laboratory Director on 03/05/2018, revealed 11 out of 61 individuals listed and certified by the Laboratory Director to fulfill the position and responsibilities of TS for the high complexity Immunology, Chemistry and Hematology testing procedures performed. 2. Review of the education documentation, provided on and within seven calendar days of the exit date of the inspection, found two out of the 11 TS's indicated did not meet the minimum education qualifications to fulfill the position and responsibilities of a TS in Immunology, Chemistry and Hematology as listed below: a) TS#4 possesses an Associate of Applied Science in Medical Laboratory Technology and does not meet the minimum education requirements to fulfill the position and responsibilities of a TS in Immunology, Chemistry and Hematology. b) TS#9 possesses a Bachelor of Science in Public Health and an Associate of Applied Science in Medical Laboratory Technology and does not meet the minimum education requirements to fulfill the position and responsibilities of a TS in Immunology, Chemistry and Hematology. 3. The LM confirmed the above mentioned education documentation for TS#4 and TS#9 were their highest levels of education achieved. The phone interview occurred on 03/13/2018 at 3:00 PM. Item 3: Based on record review and an interview with the Laboratory Manager (LM), the laboratory failed to ensure that Technical Supervisor (TS) #9 met the minimum TS qualification requirements for the high complexity testing procedures performed in the subspecialties of Bacteriology; 493.1449(c), Mycobacteriology; 493.1449(d), Mycology; 493.1449(e), Parasitology; 492.1449(f) and Virology; 493.1449(g). Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed and dated by the Laboratory Director on 03/05/2018, revealed five out of 61 individuals listed and certified by the Laboratory Director to fulfill the position and responsibilities of a TS for the high complexity Bacteriology, Mycobacteriology, Mycology, Parasitology and Virology testing procedures performed. 2. Review of the education documentation, provided on and within seven calendar days of the exit date of the inspection, found one out of the five TS's indicated did not meet the minimum education qualifications to fulfill the position and responsibilities of a TS in Bacteriology, Mycobacteriology, Mycology, Parasitology and Virology as listed below: TS#9 possesses a Bachelor of Science in Public Health and an Associate of Applied Science in Medical Laboratory Technology and does not meet the minimum education requirements to fulfill the position and responsibilities of a TS in Bacteriology, Mycobacteriology, Mycology, Parasitology and Virology. 3. The LM confirmed the above mentioned education documentation for TS#9 was their highest level of education achieved. The phone interview occurred on 03/13/2018 at 3:00 PM.

D6127

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on record review and interviews with the Laboratory Manager (LM) and Coordinator; Specimen Processing/Phlebotomy (CSP/P), the Technical Supervisor (TS) failed to evaluate and document the performance of TP#3 who was responsible for high complexity Microbiology and Immunology testing procedures at least semiannually during the first year the individual tested patient specimens. Findings Include: 1. Review of the laboratory's 2017 and 2018 training and competency assessment documentation, provided on the dates of the inspection, found TP#3 had Illumigene training records completed by TS#2 on 02/01/2017, began testing, was assessed on 10/5/2017 by TS#2, but did not find that TP#3 had a 12 month (02/2018) competency assessment conducted within the first year of testing. 2. Further review of the laboratory's 2017 training and competency assessment documentation, provided on the dates of the inspection, found TP#3 had 13 test platforms in Bacteriology, Mycobacteriology, Mycology, Parasitology and Virology training records completed by TS#9 (unqualified) on 05/26/2017, began testing, but did not find that TP#3 had any 6 month (11/2017) competency assessments conducted within the first year of testing. 3. The LM and CSP/P stated the laboratory's 2017 competency assessments and documentation of the assessments were lacking and confirmed the laboratory did not conduct and document semiannual competency assessments for TP#3 within the first year of testing, as required, by a qualified TS. The interviews occurred on 03/06/2018 at 2:30 PM.

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Item 1: Based on record review and interviews with the Laboratory Manager (LM) and Coordinator; Specimen Processing/Phlebotomy (CSP/P), the Technical Supervisor (TS) failed to evaluate and document the performance of Testing Personnel (TP) who were responsible for high complexity Microbiology and Immunology testing procedures at least annually after the first year the individuals tested patient specimens. Findings Include: 1. Review of the laboratory's 2016 and 2017 competency assessment documentation, provided on the dates of the inspection, found that 21 out of 21 TP reviewed had missing annual competency assessment records for the testing performed as listed below: TP#1, TP#5, TP#6, TP#12, TP#18, TP#20, TP#21, TP#34, TP#36 and TP#51; Immunology (2016/2017) TP#1, TP#5; gram stain (2016/2017) TP#2; all by non-qualified TS (2016) parasitology, virology (2017) TP#7, TP#19; Illumigene (2017) TP#8, TP#15, TP#22, TP#23; no competency

assessment documentation (2017) TP#11; blood culture, Binax Now, Cryptococcus, Giardia, EHEC, fecal lactoferrin (2017) TP#13; gram stain (2017) TP#17; most test platforms (2016) blood culture (2017) TP#35; IgM, Mycobacteriology, gram stain, Kirby Bauer susceptibility, Vitek, Binax Now (2016) 2. The LM and CSP/P stated the laboratory's competency assessments and documentation of the assessments were lacking and confirmed the laboratory did not conduct and document competency assessments as required. The interviews occurred on 03/06/2018 at 2:30 PM. 38953 Item 2: Based on record review and an interview with the Laboratory Manager (LM), the Technical Supervisor (TS) failed to ensure policies and procedures were followed for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing assuring they are competent and maintain their competency to process specimens, perform test procedures, and report test results promptly and proficiently. Findings Include: 1. Review of the laboratory's competency records for the specialty of Chemistry did not find any completed 2017 competency assessments for any testing personnel. 2. The LM confirmed the laboratory did not complete any chemistry competency assessments for 2017 and was unable to provide documentation on the date of the inspection. The interview occurred on 03/06/2018 at 10:30 AM. 38954 Item 3: Based on record review and an interview with the Laboratory Manager, the Technical Supervisor failed to ensure policies and procedures were followed for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing assuring they are competent and maintain their competency to process specimens, perform test procedures, and report test results promptly and proficiently in the specialty of Hematology. Findings include: 1. Review of competency assessment documentation for the specialty of Hematology found that no competency assessments were completed for the year of 2017. 2. An interview with the Laboratory Manager, on 03/06/18 at 10:30 am, confirmed no competency assessments were performed in hematology for the year of 2017. Item 4: Based on record review and an interview with the Laboratory Manager, the Technical Supervisor failed to ensure policies and procedures were followed for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing assuring they are competent and maintain their competency to process specimens, perform test procedures, and report test results promptly and proficiently in the specialty of Immunohematology. Findings include: 1. Review of competency assessment documentation for the specialty of Immunohematology found that competency assessment was not completed for Testing Personnel #1 for the year of 2017. 2. An interview with the Laboratory Manager, on 03/06/18 at 10:30 am, confirmed no competency assessment was performed in Immunohematology for Testing Personnel #1 for the year of 2017.

D6141

GENERAL SUPERVISOR
CFR(s): 493.1459

The laboratory must have one or more general supervisors who are qualified under 493.1461 of this subpart to provide general supervision in accordance with 493.1463 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and an interview with the Laboratory Manager (LM), the laboratory failed to ensure that General Supervisor (GS) #1 met the minimum qualification requirements of 493.1461(e) in the specialty of Histopathology to provide general supervision in accordance with 493.1463. Findings Include: 1. The laboratory failed to ensure that General Supervisor (GS) #1 met the minimum

qualification requirements of 493.1461(e) in the specialty of Histopathology. (Refer to D6143)

D6143

GENERAL SUPERVISOR QUALIFICATIONS

CFR(s): 493.1461

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or paragraph (b)(2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(2); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3)(i) Except as specified in paragraph (3)(ii) of this section, have previously qualified as a general supervisor under 493.1462 on or before February 28, 1992. (c)(3)(ii) Exception. An individual who achieved a satisfactory grade in a proficiency examination for technologist given by HHS between March 1, 1986 and December 31, 1987, qualifies as a general supervisor if he or she meets the requirements of 493.1462 on or before January 1, 1994. (c)(4) On or before September 1, 1992, have served as a general supervisor of high complexity testing and as of April 24, 1995-- (c)(4)(i) Meet one of the following requirements: (c)(4)(i)(A) Have graduated from a medical laboratory or clinical laboratory training program approved or accredited by the Accrediting Bureau of Health Education Schools (ABHES), the Commission on Allied Health Education Accreditation (CAHEA), or other organization approved by HHS. (c)(4)(i)(B) Be a high school graduate or equivalent and have successfully completed an official U.S. military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician). (c)(4)(ii) Have at least 2 years of clinical laboratory training, or experience, or both, in high complexity testing; or (c)(5) On or before September 1, 1992, have served as a general supervisor of high complexity testing and-- (c)(5)(i) Be a high school graduate or equivalent; and (c)(5)(ii) Have had at least 10 years of laboratory training or experience, or both, in high complexity testing, including at least 6 years of supervisory experience between September 1, 1982 and September 1, 1992. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3)(i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l) or (2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(l)(3); and

(e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(m).

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Laboratory Manager (LM), the laboratory failed to ensure that General Supervisor (GS) #1 met the minimum qualification requirements of 493.1461(e) in the specialty of Histopathology. Findings Include: 1. Review of the laboratory's Form CMS-209, approved, signed and dated by the Laboratory Director on 03/05/2018, revealed one out of 61 individuals listed and certified by the Laboratory Director to fulfill the position and responsibilities of a GS for the high complexity Histopathology testing procedures performed. 2. Review of the education documentation, provided on and within seven calendar days of the exit date of the inspection, found one out of the one GS indicated did not meet the minimum education qualifications to fulfill the position and responsibilities of a GS in Histopathology as listed below: GS#1 possesses a Bachelor of Arts with an American Society of Clinical Pathologist (ASCP) certification as a cytotechnologist and does not meet the minimum education requirements to fulfill the position and responsibilities of a GS in Histopathology. 3. The LM confirmed the above mentioned education documentation for GS#1, was their highest level of education achieved. The phone interview occurred on 03/13/2018 at 3 PM.