

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D0331885	(X3) Date Survey Completed 06/15/2022
Name of Provider or Supplier Promedica Toledo Hospital	Street Address, City, State 2130 W Central Ave Suite #300, Toledo, 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
D3007	<p>FACILITIES CFR(s): 493.1101(b)</p> <p>The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs.</p> <p>This STANDARD is not met as evidenced by:</p> <p>Item I: Based on interviews with Testing Personnel (TP) and direct observation, the lab failed to have sufficient supplies for the type and volume of testing it performs. This deficient practice had the potential to affect 10,800,000 patients tested in the specialty of Chemistry. Findings include: 1. Three out of 46 TP interviewed confirmed that the lab failed to ensure a sufficient supply of green top blood tube serum filters at the time of the complaint inspection that are essential for specimen testing performed in the specialty of Chemistry. 2.. An interview with TP #32, on 05/02/2022 at 3:23 PM revealed that the lab had run out of green top blood tube serum filters at the time of the inspection, which are essential for testing patient specimens in the specialty of Chemistry. 3. An interview with TP #34, on 05/02/2022 at 3:47 PM revealed that the lab had run out of green top blood tube serum filters, at the time of the inspection, which are essential for testing patient specimens in the specialty of Chemistry. 4. An interview with TP #37, on 05/02/2022 at 4:19 PM revealed that the lab had run out of green top blood tube serum filters at the time of the inspection, which are essential for testing patient specimens in the specialty of Chemistry. 5. Direct observation by the surveyor, on 05/02/2022 at 4:26 PM, found an empty container labeled "serum filters" in the supply room. TP #37 confirmed that these serum filters were used to test patient specimens in the specialty of Chemistry. Item II: Based on interviews and direct observation, the lab failed to have sufficient supplies for the type and volume of testing it performs. This deficient practice had the potential to affect 2,099 patients tested in the subspecialty of Bacteriology, from 09/13/2021 through 10/13/2021. Findings include: 1. Four out of 46 Testing Personnel (TP) interviewed confirmed that the lab failed to ensure a sufficient supply of glass blood</p>

culture bottles, that are essential for patient blood culture testing in the subspecialty of Bacteriology. 2. An interview with TP #5, on 05/02/2022 at 11:08 AM, confirmed that the laboratory ran out of glass blood culture bottles that could be analyzed on instrumentation in September of 2021. 3. An interview with TP #15, on 05/02/2022 at 11:59 AM, confirmed that the laboratory ran out of glass blood culture bottles that could be analyzed on instrumentation in September of 2021. TP #15 revealed that this shortage of glass blood culture bottles 'could have been avoided with proper planning.' 4. An interview with TP #35, on 05/02/2022 at 4:05 PM, confirmed that the laboratory ran out of glass blood culture bottles that could be analyzed on instrumentation. 5. A phone interview with TP #44, on 05/03/2022 at 8:00 AM, confirmed that the lab ran out of glass culture bottles in "September or October in 2021" and validated a manual blood culture procedure with plastic blood culture bottles that would not be able to be tested in the blood culture instrument. 6. The surveyor reviewed the manual blood culture procedure and validation provided via email on 05/10/2022 at 5:36 PM. Review of the "Validation of the BACT/ALERT FA PLUS and BACT/ALERT FN PLUS Bottles Using Offline Incubator" found an approval by Clinical Consultant (CC) #5 on 08/26/2021. Review of the "BC (blood culture) Offline incubation workflow" found an approval by the Lab Director (LD) on 09/22/2022. 7. An email, received on 06/09/2022 at 12:39 PM from the Metro Manager, confirmed that 2,099 patient blood cultures were analyzed and resulted via the manual blood culture procedure. These specimens were unable to be tested on the automated blood culture instrumentation and had to be subcultured daily by hand with manual biochemical testing for bacteria identification, as applicable.

D5309

TEST REQUEST
CFR(s): 493.1241(e)

If the laboratory transcribes or enters test requisition or authorization information into a record system or a laboratory information system, the laboratory must ensure the information is transcribed or entered accurately.

This STANDARD is not met as evidenced by:
Based on record review, and an interview with the Metro Manager, the laboratory failed to ensure test requisitions included the accurate date and time of specimen collection, and lab receipt when appropriate. This deficient practice affected a sample of six out of 36 patients tested in specialties Microbiology, Chemistry, and Hematology from 04/24/2022 to 04/30/2022 . Findings Include: 1. Review of the log for cerebrospinal fluid (CSF) specimens, titled "The Performance Insight Dashboard" for 04/24/2022 to 04/30/2022, received via email on 05/10/2022 at 6:30 PM found collection times not listed for CSF specimens tested. 2. The surveyor requested collections times for the CSF specimens on the "The Performance Insight Dashboard" for 04/24/2022 to 04/30/2022 via email on 06/01/2022 at 2:07 PM 3. The surveyor reviewed collection times for the CSF specimens on the new version of the "The Performance Insight Dashboard" for 04/24/2022 to 04/30/2022 provided via email on 06/03/2022 at 3:09 PM. 4. "The Performance Insight Dashboard" for 04/24/2022 to 04/30/2022 sent via email on 06/03/2022 at 3:09 PM revealed that 7 out of 36 specimens, with different laboratory accession numbers were collected and received by the lab on the same date and at the same time. Accession: F67581 Collected: 04/24/2022 6:51:00PM Received by lab: 04/24/2022 6:51:00PM Accession: F67582 Collected: 04/24/2022 6:51:00PM Received by lab: 04/24/2022 6:51:00PM Accession: M81382 Collected: 04/25/2022 10:17:00PM Received by lab: 04/25/2022 10:17:00PM Accession: M82377 Collected: 04/25/2022 10:19:00PM Received by lab:

04/25/2022 10:19:00PM Accession: T20687 Collected: 04/26/2022 7:56:00PM
Received by lab: 04/26/2022 7:56:00PM Accession: T20686 Collected: 04/26/2022 7:
56:00PM Received by the lab: 04/26/2022 7:56:00PM 5. The information provided
revealed the lab failed to ensure test requisitions included the accurate date and
time of specimen collection, and lab receipt when appropriate. 6. An email interview
with the Metro Manager, received on 06/15/2022 at 12:24 PM, confirmed that ..."the
collection times were not included on the sample so we log in "Unknown" into the
computer. The system then uses the receive time as the collect time by default."

D6033

TECHNICAL CONSULTANT-MODERATE COMPEXITY
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on record review and an interview with the Metro Manager, the laboratory failed to ensure that Technical Consultant (TC) #37 met the minimum qualification requirements in the specialty of Microbiology. This deficient practice had the potential to affect 875,000 patients tested under the specialty of Microbiology. Findings include: 1. The laboratory failed to ensure that TC #37 met the minimum qualification requirements in the specialty of Microbiology. (Refer to D6035)

D6035

TECHNICAL CONSULTANT QUALIFICATIONS
CFR(s): 493.1411

(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(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 (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, 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 (b)(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 (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant 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, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.

This STANDARD is not met as evidenced by:
Based on record review and an interview with the Metro Manager, the laboratory failed to ensure Technical Consultant (TC) #37 met the minimum qualification requirements. This deficient practice had the potential to affect 875,000 patients tested under the specialty of Microbiology. Findings include: 1. Review of the CMS-209 Personnel Report found TC #37 also listed as Technical Supervisor (TS) #34 and Testing Personnel (TP) #61 under the speciality of Microbiology. 2. Review of education documents failed to find education documents for TC #37 (also TS #34 and TP #61). 3. The Metro Manager confirmed via an email, sent 05/24/2022 at 2:18 PM, that the laboratory failed to locate a degree for TC #37 (also TS #34 and TP #61).

D6076

LABORATORY DIRECTOR
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:
The Laboratory Director (LD) failed to provide overall management and direction of the laboratory. This deficient practice had the potential to affect 16,173,000 patients tested in 6 out of 6 specialties, including Histocompatibility, Microbiology, Diagnostic Immunology, Chemistry, Hematology and Pathology. Findings include: 1. The LD failed to employ a sufficient number of lab personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. (Refer to D6101, Item I) 2. The LD failed to employ a sufficient number of lab personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. (Refer to D6101, Item II) 3. The LD failed to ensure all personnel have the appropriate education documentation. (Refer to D6102)

D6101

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(11)

The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart.

This STANDARD is not met as evidenced by:

Item I: Based on interviews Testing Personnel (TP) and record review, the Laboratory Director (LD) failed to employ a sufficient number of lab personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This deficient practice had the potential to affect 16,173,000 patients tested in the specialties Microbiology, Diagnostic Immunology, Chemistry, Hematology and Pathology. Findings include: 1. Via interviews conducted with laboratory staff, on 05/02/2022 from 10:32 AM through 5:11 PM, 33 out of 43 considered the laboratory to be short-staffed. This included TP #1, #7, #8, #18, #21, #26, #28, #33, #34, #38, #43, #46, #66, #70, #72, #74, #77, #85, #87, #89 #93 and processors #1, #2, #3, #4, #5, #7, #8, #9, #10, #11, # 12 and #13. 2. Via phone interviews conducted with laboratory staff, on 05/03/2022 at 8:00 AM, on 5/12/2022 at 1:00 PM and on 05/17/2022 at 2:31 PM, 3 out of 3 considered the laboratory to be short staffed. This included TP #80, #14 and #29. 3. Seven out of the total 46 laboratory personnel interviewed considered staffing shortages to have negatively impacted patient care. This included TP #33, #74, #81 and processors #3, #4, #5 and #6. 4. Ten (10) out of the total 46 laboratory personnel interviewed reported working an unplanned long shift in the past 6 weeks. This included TP #22, #28, #62, #74, #80, #93 and processor #1, #5, #8 and #11. 5. Staffing schedules, provided via email on 05/03/2022 at 5:30 PM, from 02/13/2022 through 04/03/2022 were reviewed. Five (5) out of 5 schedules reviewed, entitled "Biochemical Pathology Weekend Schedule" failed to find staff assigned to third shift from "20:30" through "23:00." 6. Central processing schedules, provided via email on 05/03/2022 at 5:30 PM, from 10/03/2021 through 04/16/2022 were reviewed. On 10/03/2021 one staff member was scheduled from "10:00 - 22:30." This left 06:30 - 10:00 unstaffed, and 22:30 - 24:30 unstaffed. On 11/20/2021, one staff member was scheduled from "10:00 - 22:30." On the same day, another staff member was scheduled from "07:00 - 19:30." On 11/20/2021, this left 06:30 - 07:00 and 22:30 - 24:00 unstaffed. 7. Microbiology and microbiology processing schedules, provided via email on 05/03/2022 at, 5:30 PM for 09/26/2021 through 11/13/2021 were reviewed. On the following days, the lab failed to have staff on the microbiology processing schedule: 09/22/2021, 09/25/2021, 10/23/2021, 10/24/2021, 02/08/2022, 02/12/2022, 02/17/2022, 02/18/2022. Item II: Based on interviews and record review, the Laboratory Director (LD) failed to employ a sufficient number of lab personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This deficient practice had the potential to affect 16,173,000 patients tested in the specialties Microbiology, Diagnostic Immunology, Chemistry, Hematology and Pathology. Findings include: 1. Interviews were conducted with laboratory staff, on 05/02/2022 from 10:32 AM through 5:11 PM. 17 out of 43 interviewed on 05/02/2022 confirmed that due to low staffing levels the laboratory failed to meet turnaround time targets set by the lab. This included Testing Personnel (TP) #1, #7, #8, #14, #21, #22, #33, #70, #74, #81, and processor #1, #3, #4, #5, #6, #7, #10. 2. Turnaround time data was reviewed, provided via email on 05/05/2022 at 4:46 PM, for 'CP (Central Processing) to Chem (Chemistry) Passing Percent (%) ER (Emergency Room) BMPs (Basic Metabolic Panel) 12 week Trend' from the 12/19/2021 through 02/26/2022. Over 70% of the specimens failed to make the turnaround time of less than ten minutes to travel from Central Processing to Chemistry. 3. Turnaround time data was reviewed, provided via email on 05/05/2022 at 4:46 PM, for 'CP (Central Processing) to DXH (Hematology Instrument) Passing % ER (Emergency Room) CBCs (Complete Blood Count) 12 week Trend' from the 12/19/2021 through 02/26/2022. Over 40% of specimens failed to make the turnaround time of less than ten minutes to travel from

Central Processing to Hematology. 4. "The Performance Insight Dashboard for CSF (cerebrospinal fluid)" specimens was reviewed for the week of 04/24/2022 to 04/29/2022, provided via email on 05/05/2022 at 4:46 PM. 13 out of 13 CSF specimens for gram stain failed to meet the one hour turnaround time, per the policy. 5. The "Sterile Body Fluids 'STAT' Gram Stains April 24th 2022 - April 30th 2022 with Central Processing, Receipt in Micro and Result Times" data was reviewed, provided via email on 05/05/2022 at 4:46 PM. 60 specimens out of 61 failed to be resulted in under an hour. 51 specimens out of 61 failed to be tracked when they were dropped off in Central Processing. 6. Turnaround time data was reviewed, provided via email on 05/05/2022 at 4:46 PM, for ER (Emergency Room) specimens, time in lab to time resulted. In October 2021, November 2021, December 2021, January 2022, February 2022 and March 2022, turnaround time failed to meet the 85% turnaround time target set by the lab. 7. Turnaround time data was reviewed, provided via email on 05/05/2022 at 4:46 PM, for Infectious Disease specimens, from time in the lab to time resulted. In December of 2021, turnaround time failed to meet the 85% turnaround time target set by the lab. 8. PAP (pap smear) turnaround time data was reviewed, provided via email on 05/05/2022 at 4:46 PM, for Cytology, from time in lab to time resulted. In October, November and December of 2021, PAP specimens failed to meet the turnaround time target set by the lab. 9. Routine Surgical turnaround time data was reviewed, provided via email on 05/05/2022 at 4:46 PM, from time in lab to time resulted. In October and November of 2021, the lab failed to meet target turnaround time is 85% of specimens meeting the 48 hour turnaround time target.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on record review and an email interview, the Laboratory Director failed to ensure all personnel have the appropriate education documentation. This deficient practice affected two out of 96 personnel listed on the CMS-209 Personnel Report Form in the specialties of Chemistry and Microbiology. Findings include: 1. Review of the CMS-209 Personnel Report found Testing Personnel (TP) #16 also listed as General Supervisor (GS) #14 under the speciality of chemistry. 2. Review of the CMS-209 Personnel Report found TP #61 also listed as Technical Consultant (TC) #37 and Technical Supervisor (TS) #34 under the speciality of microbiology. 3. Review of education documents found a BA degree with a major of "Environmental Policy and Analysis" and a certificate that stated "AS degree earned." Note: A BA degree with a a major of Environmental Policy and Analysis does not qualify as a bachelor degree in a [human] biological, chemical or physical science. The certificate showed classes taken in medical laboratory science; however did not show the 60 credit hours total to qualify as an associate's degree; nor did it state the major of the associates degree. 4. Review of education documents failed to find education documents for TP # 61 (also TC #37 and TS #34). 5. Via an email on 05/23/2022 at 11:31 AM, the surveyor requested education documents from TP #16 (also GS #14), and TP #61 (also TC #37 and TS #34). 6. The Metro Manager confirmed via an email interview, sent 05/24/2022 at 2:18 PM, that the laboratory failed to locate a degree for TP #61 (also TC #37

and TS #34), and failed to locate further information on TP #16 (also GS #14) major of study for the AS degree.

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 Metro Manager, the laboratory failed to ensure that Technical Supervisor (TS) #34 met the minimum qualification requirements in the specialty of Microbiology. This deficient practice had the potential to affect 875,000 patients tested under the specialty of Microbiology. Findings include: 1. The laboratory failed to ensure that Technical Supervisor (TS) #34 met the minimum qualification requirements in the specialty of Microbiology. (Refer to D6111)

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: (l)(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-- (l)(3)(i)(B) Must meet one of the following requirements: (l)(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 (l)(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 (l)(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:

Based on record review and an email interview, the laboratory failed to ensure Technical Supervisor (TS) #34 met the minimum qualification requirements. This deficient practice had the potential to affect 875,000 patients tested under the specialty of Microbiology. Findings include: 1. Review of the CMS-209 Personnel Report found TS #34 also listed as Technical Consultant (TC) #37 and Testing Personnel (TP) #61 under the speciality of Microbiology. 2. Review of education documents failed to find education documents for TS #34 (also TC #37 and TP #61). 3. The Metro Manager confirmed via an email, sent 05/24/2022 at 2:18 PM, that the laboratory failed to locate a degree for TS #34 (also TC #37 and TP #61).

D6168

TESTING PERSONNEL

CFR(s): 493.1487

The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed.

This CONDITION is not met as evidenced by:

Based on review of the laboratory's Form CMS-209 and education documentation, the laboratory failed to ensure Testing Personnel (TP) #16 and TP #61 met the qualification requirements of 493.1489 for high complexity testing. This deficient practice had the potential to affect 10,800,000 patients tested in the specialty of Chemistry and 875,000 patients tested in the specialty of Microbiology. Findings Include: 1. The laboratory failed to ensure TP #16 met the high complexity testing personnel qualification requirements. (Refer to D6171 Item I) 2. The laboratory failed to ensure TP #61 met the high complexity testing personnel qualification requirements. (Refer to D6171 Item II)

D6171

TESTING PERSONNEL QUALIFICATIONS

CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for

proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Item I: Based on record review and an email interview, the laboratory failed to ensure all personnel met the appropriate educational requirements. This deficient practice had the potential to affect 10,800,000 patients tested under the specialty of chemistry. Findings include: 1. Review of the CMS-209 Personnel Report found TP #16 also listed as General Supervisor (GS) #14 under the speciality of Chemistry. 2. Review of education documents found a BA degree with a major of "Environmental Policy and Analysis" and a certificate that stated "AS degree earned." Note: A BA degree with a a major of Environmental Policy and Analysis does not qualify as a bachelor degree in a [human] biological, chemical or physical science. The certificate showed classes taken in medical laboratory science; however did not show the 60 credit hours total to qualify as an associate's degree; nor did it state the major of the associates degree. 3. The Metro Manager confirmed via an email, sent 05/24/2022 at 2:18 PM, that the lab failed to locate further information on TP #16 (also GS #14) major of study for the AS degree. Item II: Based on record review and an email interview, the laboratory failed to ensure all personnel met the appropriate educational requirements. This deficient practice had the potential to affect 875,000 patients tested under the specialty of Microbiology. Findings include: 1. Review of the CMS-209 Personnel Report found TP #61 also listed as Technical Consultant (TC) #37 and Technical Supervisor (TS) #34 under the speciality of Microbiology. 2. Review of education documents failed to find education documents for TP # 61 (also TC #37 and TS #34). 3. The Metro Manager confirmed via an email, sent 05/24/2022 at 2:18 PM, that the laboratory failed to locate a degree for TP #61 (also TC #37 and TS #34).