

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2157771	(X3) Date Survey Completed 04/12/2022
Name of Provider or Supplier Molecular Stat Laboratory, Inc	Street Address, City, State 4373 Nw 124th Ave, Coral Springs, FL	
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
D0000	A complaint survey for 2022002865 was conducted on 3/8/2022-4/12/2022 at Molecular Stat Laboratory. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following Conditions were not met: D2016-Successful Participation. D5400-Analytic Systems. D6076-Laboratory Director. D6108-Laboratory Technical Supervisor. D6141-General Supervisor.
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory's proficiency testing (PT) records for 2021, the laboratory did not have successful performance in Proficiency Testing in the specialty of Hematology (Refer to D2131) and in the subspecialty of Endocrinology (Refer to</p>

	<p>D2108) Findings included: Review of American Proficiency Institute (API) PT records for 2021, revealed a score of 0 percent (%) for the second and third event of Hematology. Review of College of American Pathologists (CAP) records for 2021, revealed a score of 48 % and 0 % in the second and third event of 2021 respectively for the subspecialty of Endocrinology. During an interview on 03/10/2022 at 2:30 PM, the laboratory manager confirmed that the laboratory failed the events of reference.</p>
D2025	<p>BACTERIOLOGY CFR(s): 493.823(c)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to submit the proficiency testing results for the subspecialty of Bacteriology for the third event of 2021. Findings included: Review of College of American Pathologists (CAP) proficiency testing (PT) records revealed that the laboratory failed to submit the results for Bacteriology in the third event of 2021 resulting in a zero percent score. During an interview on 03/10/2022 at 02:05 PM, the laboratory manager confirmed that the laboratory failed to submit the results for the event of reference.</p>
D2061	<p>VIROLOGY CFR(s): 493.831(c)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to submit the proficiency testing results for the subspecialty of Virology for the third event of 2021. Findings included: Review of College of American Pathologists (CAP) proficiency testing (PT) records revealed that the laboratory failed to submit the results for Virology in the third event of 2021 resulting in a zero percent score. During an interview on 03/10/2022 at 02:08 PM, the laboratory manager confirmed that the laboratory failed to submit the results for the event of reference.</p>
D2081	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(d)</p> <p>Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to submit the proficiency testing results for the specialty of Immunology for the third event of 2021. Findings included: Review of College of American Pathologists (CAP) proficiency testing (PT)</p>

	<p>records revealed that the laboratory failed to submit the results for Immunology in the third event of 2021 resulting in a zero percent score. During an interview on 03/10/2022 at 02:08 PM, the laboratory manager confirmed that the laboratory failed to submit the results for the event of reference.</p>
<p>D2108</p>	<p>ENDOCRINOLOGY CFR(s): 493.843(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not have satisfactory results for the subspecialty of Endocrinology in 2021. Findings included: Review of College of American Pathologists (CAP) proficiency testing (PT) records revealed that the laboratory had 48% and 0% in the second and third event of 2021 respectively. During an interview on 03/10/2022 at 02:08 PM, the laboratory manager confirmed that the laboratory had failed the events of reference.</p>
<p>D2131</p>	<p>HEMATOLOGY CFR(s): 493.851(g)</p> <p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory did not have successful participation in proficiency testing for the specialty of Hematology in 2021. Findings included: Review of American Proficiency Institute (API) proficiency testing (PT) records revealed that the laboratory had 0 percent (%) score for Hematology, Cell Identification or White Blood Differential, Red Blood Cell, Hematocrit, Hemoglobin, White Blood Cells and Platelets for the second and third event of 2021. During an interview on 03/10/2022 at 02:00 PM, the laboratory manager confirmed that the laboratory had the failed a 0% score for the Hematology specialty for the events of reference because the lab failed to submit the tests results.</p>
<p>D5217</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on lack of records and general supervisor (GS) interview, the laboratory failed to verify the accuracy of testing methods at least twice annually for 46 out of 46 analytes tested in urine toxicology in 2021. Findings included: -Review of test menu reported to COLA on 08/19/2021 for Urine Toxicology revealed that the laboratory listed the following analytes: 6-Acetylmorphine-Heroin, Amphetamine, Barbiturates,</p>

Benzodiazepine, Buprenorphine, Cannabinoid, Cocaine, Ethyl Glucuronide, Methadone, Opiates, Oxycodone, Tricyclics, 7-Aminoclonazepan, Alpha-hydroxyalprazolam, Benzoylecgonine, Butalbital, Buprenorphine, Carisoprodol, Codeine, Cyclobenzaprine, 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP), Fentanyl, Gabapentin, Hydrocodone, Hydro morphine, 3,4-Methylenedioxy-N-ethylamphetamine (MDEA), Meprobamate, Methadone, Methamphetamine, Morphine, Norbuprenorphine, Nordiazepam, Norfentanyl, Norhydrocone, Norxycodone, O-Desmethyl-Tramadol, Oxyazepam, Oxymorphone, Phencyclidine (PCP), Phenobarbital, Pregabalin, Sertraline, Tapentadol, Temazepam, Tramadol, 11-nor-9-carboxy-delta-tetrahydrocannabinol (THC-COOH), Ethyl sulphate. -Patient record review revealed that the laboratory tested 46 patients for urine Toxicology during 2021. During an interview on 03/10/2022 at 2:10 PM with GS, she confirmed that the laboratory failed to perform at least twice a year accuracy verification for the analytes tested in Urine Toxicology during 2021.

D5400

ANALYTIC SYSTEMS
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:
Based on record review and interview, the laboratory failed to complete a validation for the following tests: Aptima SARS-CoV-2 Assay on the Panther system, Determination of SARS-CoV-2 (COVID-19) using Real-Time Polymerase Chain Reaction (RT-PCR) and SARS-CoV-2 RNA STAR Complete before specimen testing since 12/20/2021. (See D5423) Based on record review and observation, the laboratory failed to run positive and negative controls for unvalidated SARS-CoV-2 RNA STAR Complete with the Quant Studio 5 in COVID-19 polymerase chain reaction (PCR) testing since 1/19/2022. (See D5455)

D5423

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(2)

Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to complete a validation

for the following tests: Aptima SARS-CoV-2 Assay on the Panther system, Determination of SARS-CoV-2 (COVID-19) using Real-Time Polymerase Chain Reaction (RT-PCR) and SARS-CoV-2 RNA STAR Complete before specimen testing since 12/20/2021. Findings Included: Review of Verification Summary for Aptima SARS-CoV-2 using the Hologic Panther instrument serial number 10497 (written as seen) revealed the validation method comparison worksheets for accuracy and precision pages were not completed. Missing from the pages were worklist ID, Panel ID, dates and operators. The laboratory director signed the document on 12/16/2021. Review of Panther Fusion Instrument worksheets revealed that the laboratory started testing COVID-19 specimen on 12/20/2021 at 9:50 PM. Review of Verification Summary for Determination of SARS-CoV-2 (COVID-19) using Real-Time Polymerase revealed there was no written documentation along with instrument printouts of a validation done with the instrument alpha -272532153. The laboratory director signed the document on 8/20/2021. Review of In-house COVID-19 Testing log revealed COVID-19 specimens were tested with the Determination of SARS-CoV-2 (COVID-19) using Real-Time Polymerase method from 8/12/2021 to 10/6/2021. Review of SARS-CoV-2 RNA STAR Complete Validation revealed no written documentation along with Quant Studio 5 instrument printouts of a validation completed. No laboratory director signature on the validation. Review of 2022 COVID-19 Plate Maps and instrument printouts revealed the System using the SARS-CoV-2 RNA STAR to test for COVID-19 since 1/19/2022. Review of CMS-116 Form revealed 300,000 specimens were tested for COVID-19 from 12/20/2021 to present. During an interview on 3/10/2022 at 10:50 AM, the general supervisor confirmed Aptima SARS-CoV-2 Assay on the Panther system, Determination of SARS-CoV-2 (COVID-19) using Real-Time Polymerase Chain Reaction (RT-PCR) and SARS-CoV-2 RNA STAR Complete validations were not completed before testing for COVID-19.

D5455

CONTROL PROCEDURES
CFR(s): 493.1256(d)(3)(v)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on record review and observation, the laboratory failed to run positive and negative controls for unvalidated SARS-CoV-2 RNA STAR Complete with the Quant Studio 5 in COVID-19 polymerase chain reaction (PCR) testing since 01/19/2022. The lab reported 300,000 test results. Findings Included: Review of SARS-CoV-2 RNA STAR Complete Test instructions stated "Quality control procedures are intended to monitor reagent and assay performance. Test all Positive and Negative Controls Media when running diagnostic samples and with each new lot of the LumiraDx SARS CoV-2 RNA STAR Complete kit to ensure all reagents and kit components are work." Review of "Schedule for Quality Assurance/Quality [sic] Control Programs" stated "purpose is to set up a schedule for the overall quality control and quality assurance program. The following schedules are observed for the Quality Control Program: 1. Daily: D. Commercial controls run." Review of 2022

Daily/Monthly QC Log for SARS-Cov2 revealed worklist ID was missing from quality control 01/19/2022-03/09/2022. Review of 2022 January-March Quant studio 5 instrument COVID-19 results printouts displayed no controls run on the instrument from 01/19/2022 to March 03/09/2022. Specimens and controls could not be identified from the test printouts Review of 2022 January-March COVID-19 specimen worklist revealed the worklists had no correction to the Quant studio 5 instrument COVID-19 results printouts. Specimens and controls that were placed in the worksheet did not match with Quant studio 5 instrument printouts. Review of CMS-116 Form revealed 300,000 specimens were tested for COVID-19 from 12/20/2021 to present. During an interview on 03/10/2022 at 10:51 AM, the General Supervisor confirmed positive and negative controls were not run the for unvalidated SARS-CoV-2 RNA STAR Complete with the Quant Studio 5 in COVID-19 polymerase chain reaction (PCR) testing since 01/19/2022.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory Quality Assurance (QA) failed to identify and correct the failures in proficiency testing (PT), failure in method validation and failure in personnel. Findings included: -Review of QA policy revealed that the laboratory will perform monthly QA checklist to assess the laboratory performance. - Review of monthly checklists for year 2021 revealed that they failed to reflect and correct the laboratory deficiencies. Refer to D2131, D2108, D5421 and D6120. During an interview on 03/10/2022 at 04:05 PM, the Laboratory Manager confirmed that the laboratory QA failed to correct the deficiencies listed above.

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:
Based on record review and staff interview, the laboratory director failed to effectively oversee the laboratory from 2021 to 2022. Findings included: -Failed to ensure the laboratory had successful participation in proficiency testing (PT) for the specialty of Hematology and the subspecialty of Endocrinology in 2021. Refer to D6089. -Failed to ensure the laboratory submitted on time the PT results for Bacteriology, Virology, and General Immunology. Refer to D6090 -Failed to ensure complete test validation before testing patients. Refer to D6086.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on record review and interview, the laboratory director failed to ensure a validation was completed for the following tests: Aptima SARS-CoV-2 Assay on the Panther system, Determination of SARS-CoV-2 (COVID-19) using Real-Time Polymerase Chain Reaction (RT-PCR) and SARS-CoV-2 RNA STAR Complete before specimen testing since 12/20/2021. Findings included: Based on record review and interview, the laboratory failed to complete a validation for the following tests: Aptima SARS-CoV-2 Assay on the Panther system, Determination of SARS-CoV-2 (COVID-19) using Real-Time Polymerase Chain Reaction (RT-PCR) and SARS-CoV-2 RNA STAR Complete before testing since 12/20/2021. (See D5423) Based on record review and observation, the laboratory failed to run positive and negative controls for unvalidated SARS-CoV-2 RNA STAR Complete with the Quant Studio 5 in COVID-19 polymerase chain reaction (PCR) testing since 01/19/2022.(See D5455) During an interview on 03/10/2022 at 10:56 AM, the owner confirmed the validations were not completed for the following: Aptima SARS-CoV-2 Assay on the Panther system, Determination of SARS-CoV-2 (COVID-19) using Real-Time Polymerase Chain Reaction (RT-PCR) and SARS-CoV-2 RNA STAR Complete before testing since 12/20/2021.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's proficiency testing (PT) scores, the laboratory director (LD) failed to ensure that the laboratory performed PT in such a manner as to achieve and maintain successful participation in PT for the subspecialty of Endocrinology (Refer to D2108) and the specialty of Hematology (Refer to D2131)

D6090

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(ii)

The laboratory director must ensure the results are returned within the timeframes established by the proficiency testing program.

This STANDARD is not met as evidenced by:

Based on record review and staff interview the laboratory director failed to ensure that all proficiency testing (PT) results were submitted to the proficiency agencies in 2021 for the specialty of Hematology and the subspecialties of General Immunology, Endocrinology, Virology, and Bacteriology. Findings included: Review of PT records for American Proficiency Institute (API) and College of American Pathologists (CAP) for 2021 revealed that the laboratory failed to submit results for Bacteriology, General Immunology, Hematology, Endocrinology and Virology. Refer to D2025, D2061, D2081, D2108 and D2131.

<p>D6094</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the Laboratory Director (LD) failed to ensure the Quality Assessment (QA) identified and corrected problems in proficiency testing and analytic systems. Findings included: Cross reference to D6090, D5423 and D5791.</p>
<p>D6108</p>	<p>LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on record review and staff interview the laboratory failed to have a qualified Technical Supervisor (TS). Refer to D6111</p>
<p>D6111</p>	<p>TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449</p> <p>(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</p>

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 or 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 (1)(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 (1)(2)(ii) An individual qualified under 493.1449(b) or paragraph (1)(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 (1)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (1) (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:

Based on record review and staff interview, the laboratory failed to have a qualified Technical Supervisor (TS) from August 2021 to present. Findings include: - Review of CMS-209 FORM, Laboratory Personnel Report dated and signed by the Laboratory Director on 03/10/2022 revealed that the Technical Supervisor (TS) is acting under

the Virology Subspecialty. -Review of current test menu for the laboratory, revealed that the laboratory is performing virus SARS CoV2 testing. - Review of Delegation Function signed by the laboratory director on 10/02/2020 designates the TS as the person in charge when he is absent from the laboratory. -Review of the Technical Supervisor license revealed that he does not have the Microbiology Specialty . - During an interview on 03/10/2022 at 4:10 PM, the laboratory manager confirmed that the TS does not have the Microbiology Specialty.

D6120

TECHNICAL SUPERVISOR RESPONSIBILITIES
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Technical Supervisor (TS) failed to sign competency assessment for four out of five Testing Personnel (TP) in 2022 and failed to ensure the laboratory had complete records for current and previous TP during 2021. Findings included: -Review of CMS-209 form, Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 03/10/2022 revealed that: -The laboratory is currently performing tests under the Virology Subspecialty. - The LD and Clinical Consultant was the same person, there was one Technical Supervisor (TS) and one General Supervisor (GS) and five Testing Personnel (TP) (#A, # B, #C, #D and # E). -Review of personnel folder for TP #B revealed no documentation of the hiring date, no competencies for chemistry and hematology for 2021. Review of seven complete blood cell counts (CBC # 1, CBC # 2, CBC # 3, CBC # 4, CBC # 5, CBC # 6 and CBC # 7) performed on Abacus 5 Instrument during September, October, November and December of 2021 revealed that they were released by TP #B, review of Proficiency Testing (PT) records for 2021 revealed that TP # B performed the Chemistry third event (C-C). -Review of TP #E folder revealed no records for competencies for 2021, PT records review revealed that she performed the first event for Chemistry for 2021, no competencies found for that period of work. -Review of competencies for TP #A, #B, #C and #E, revealed that the evaluation on January 2022 for Quantum Instrument was signed by the GS listed on the CMS 209 form, signing as TS. -Review of Proficiency Testing (PT) and personnel records revealed that four former TP (#1, #2, #3, #4) had incomplete personnel records: a) TP #1 hired 08/03 /2021, resigned on 10/01/2021 performed PT on 2021 Event CM-B, no competencies records found. b) TP #2 hired on December 2021, resigned in January 2022, she performed SARs CoV-2 tests on the Panther had no competency for the period of reference. c) TP #3 hired on 03/17/2021, participated in PT in 2021 and resigned on 01 /28/2022 had one competency on 03/17/2021 no other competencies found. d) TP #4 hired 01/08/2021, resigned 08/21/2021, he performed PT on 04/09/2021 for the Respiratory Infectious Disease panel, no competencies found. During an interview on 03/10/2022 at 1:25 PM, the Laboratory Manager confirmed that the TS failed to sign the competency assessments of reference and failed to ensure the laboratory had documentation of the competencies of former employees, he explained that the laboratory is under a new owner and new management and they failed to ensure to have complete documentation.

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 staff interview the laboratory failed to have a qualified General Supervisor (GS). 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(1)(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 staff interview, the laboratory failed to have a qualified General Supervisor (GS) from August 2021 to present. Findings included: - Review of CMS-209 FORM, Laboratory Personnel Report dated and signed by the Laboratory Director on 03/10/2022 revealed that the laboratory is working under the Virology subspecialty. -Review of current test menu for the laboratory, revealed that the laboratory is performing virus SARS CoV2 detection. -Review of the Florida license for the GS listed in the CMS-209 FORM revealed that she does not have the Microbiology specialty . During an interview on 03/10/2022 at 4:15 PM, the laboratory manager confirmed that the GS does not have the Microbiology Specialty.