Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	23D2209166	04/14/2022
Name of Provider or Supplier	**Street Address, City, State**	
Taylor Diagnostics Imaging	28300 Franklin Road Suite 100, Southfield, MI	

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
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: . Based on observation, record review, and interviews, the laboratory failed to meet applicable facilities requirements and correct identified problems. Findings include: 1. The laboratory failed to employ a uni-directional workflow and have separate areas for specimen and reagent preparation for its iAMP COVID-19 Detection Kit open system SARS-CoV-2 Real-Time PCR molecular test system. Refer to D3005.
D3005	FACILITIES CFR(s): 493.1101(a)(3) Molecular amplification procedures that are not contained in closed systems have a uni-directional workflow. This must include separate areas for specimen preparation, amplification and product detection, and, as applicable, reagent preparation. This STANDARD is not met as evidenced by: . Based on observation and interview with the General Supervisor, the laboratory

	failed to employ a uni-directional workflow and have separate areas for specimen and reagent preparation for its iAMP COVID-19 Detection Kit open system SARS-CoV-2 Real-Time PCR molecular test system for 6 (October 2021 to April 2022) of 6 months the laboratory has been performing molecular testing. Findings include: 1. The surveyor observed the laboratory's BioRad C1000 Touch Thermal Cycler used in COVID-19 testing, not a closed system, on 4/14/22 at 8:53 am. 2. TP3 verbally demonstrated the testing process using the BioRad C1000 Touch Thermal Cycler on 4 /14/22 at 9:02 am. TP3 indicated the laboratory uses one hood for both specimen and reagent preparation. The trash for the post amplification PCR plates is kept near the hood, requiring staff to cross back into the specimen and reagent preparation area to discard used, post amplification PCR plates. 3. An interview on 4/14/22 at 9:02 am with TP3 confirmed the laboratory did not use a unidirectional workflow and have separate areas for specimen and reagent preparation for its open system molecular testing.
D5427	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(c) (c) Documentation. The laboratory must document all activities specified in this section. This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to document the run data used in the verification of performance specifications of the iAMP COVID-19 Detection Kit test system for 6 (October 2021 to April 2022) of 6 months the test system has been in use. Findings include: 1. A review of the laboratory's iAMP COVID-19 Detection Kit verification of performance specifications revealed a lack of run data documentation used in the accuracy, precision, analytic specificity, and analytic sensitivity studies. 2. An interview on 4/14 /22 at 11:51 am with the General Supervisor confirmed the run data used in the verification of performance specifications was not available.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: . A. Based on record review and interview with the General Supervisor, the laboratory failed to provide patients with the authorized Fact Sheets for the interpretation of test results for 6 (October 2021 to April 2022) of 6 months the laboratory has been using Emergency Use Authorized SARS-CoV-2 test systems. Findings include: 1. A review of the laboratory's "iAMP COVID-19 Detection Kit" Instructions For Use (IFU) revealed a section stating, "Authorized laboratories using your product will include

	with result reports of your product, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 2. A review of the laboratory's "QIAstat-Dx Respiratory SARS-CoV-2 Panel Instructions for Use (Handbook)" revealed a section stating, "Authorized laboratories using your product must include with result reports of your product, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 3. A review of 19 patient test reports revealed a lack of documentation that the authorized Fact Sheets were given to patients with their results. 4. An interview on 4/14/22 at 2:18 pm with the General Supervisor revealed the laboratory had not been issuing all authorized Fact Sheets with the patient test results for the QIAstat-Dx Respiratory SARS-CoV-2 Panel or the iAMP COVID-19 Detection Kit. B. Based on record review and interview with the General Supervisor, the laboratory failed to ensure positive patient identification and indicate the name and the address of the laboratory on test reports for 4 (Patients RSP21-00066, RSP21-00254, RSP22-00112, RSP22-00203) of 19 patient test reports reviewed. Findings include: 1. A review of patient test reports for patients receiving testing with the QIAstat-Dx Respiratory SARS-CoV-2 Panel revealed a lack of two patient identifiers and the laboratory name and address for the following patients: a. Patient RSP21-00066 tested on 11/30/2021. b. Patient RSP21-00254 tested on 12/21/2021. c. Patient RSP22-00112 tested on 01/25/2021. d. Patient RSP22-00203 tested on 03/05/2022. 2. An interview on 4/14/22 at 2:21 pm with the General Supervisor confirmed the test reports for the patients listed above did not ensure positive patient identification or have the name and address of the laboratory.
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 interview with the General Supervisor, the laboratory failed to ensure the Laboratory Director, performing the duties of a Technical Consultant, and the Technical Consultant met the qualification requirements at 493.1411. Findings include: 1. The laboratory failed to ensure personnel performing the Technical Consultant duty of performing testing personnel competency assessments was qualified. Refer to D6035 A. 2. The laboratory failed to ensure the Technical Consultant was qualified. Refer to D6035 B.
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:
. A. Based on record review and interview with the General Supervisor, the laboratory failed to ensure personnel performing the Technical Consultant duty of performing testing personnel competency assessments was qualified for 1 (Laboratory Director) of 1 personnel performing competency assessments. Findings include: 1. A review of the laboratory's personnel competency records revealed the Laboratory Director had performed competency assessments for Testing Personnel #1 and Testing Personnel #3 on 12/20/21 and 12/21/21 respectively. 2. A review of the qualifications for the Laboratory Director revealed a lack of at least one year of training or experience in non-waived testing in microbiology and virology. 3. A review of the laboratory's "Personnel" policy revealed a section stating, "All duties are performed by qualified staff according to established policies and procedures." 4. The surveyor requested documentation of training or experience in nonwaived microbiology and virology testing on 4/14/22 at 9:52 am and it was not made available. 5. An interview on 4/14 /22 at 9:52 am with the General Supervisor revealed the Laboratory Director's documentation of training or experience in microbiology and virology testing was not available. 6. The laboratory was given an additional 7 days to provide the remaining documentation and it was not received. B. Based on record review and interview with the General Supervisor, the laboratory failed to ensure the Technical Consultant was qualified for 1 of 1 Technical Consultant listed on Form CMS-209. Findings include: 1. A review of the laboratory's personnel records revealed the Technical Consultant listed on Form CMS-209 was hired in January 2021. 2. A review of the Technical Consultant's qualifications revealed a lack of documentation showing they had completed at least 2 years of laboratory training or experience, or both in non-waived testing, in bacteriology and virology. 3. The surveyor requested the additional documentation showing the Technical Consultant met the qualification requirements on 4/14/22 at 9:54 am and they were not made available. 4. An interview on 4/14/22 at 2:12 pm with the General Supervisor confirmed the laboratory did not have the

	qualification documentation to determine the Technical Consultant was qualified. 5. The laboratory was given an additional 7 days after the survey to provide the additional qualification documentation and it was not received.
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 interview, the Laboratory Director failed to provide the laboratory with overall management and direction. Findings include: 1. The Laboratory Director failed to ensure the physical and environmental conditions of the laboratory provided a safe environment that protected employees from biological hazards. Refer to D6084. 2. The Laboratory Director failed to ensure a quality control program was established for the QIAstat-Dx Respiratory SARS-CoV-2 Panel. Refer to D6093 A. 3. The Laboratory Director failed to ensure quality control programs were maintained for the iAMP COVID-19 Detection Kit test system. Refer to D6093 B. 4. The Laboratory Director failed to ensure testing personnel had the appropriate training to accurately perform testing using the iAMP COVID-19 Detection Kit and the QIAstat-Dx Respiratory SARS-CoV-2 Panel test systems. Refer to D6101.
D6084	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(2) The laboratory director must ensure that the physical plant and environmental conditions provide a safe environment in which employees are protected from physical, chemical, and biological hazards. This STANDARD is not met as evidenced by: . Based on record review, observation, and interviews, the Laboratory Director failed to ensure the physical and environmental conditions of the laboratory provided a safe environment that protected employees from biological hazards for 6 (October 2021 to April 2022) of 6 months the laboratory has been in operation. Findings include: 1. The surveyor observed the laboratory's MyStaire Clean Prep dead air box on 4/14/22 at 8: 53 am during a tour of the laboratory. 2. An interview on 4/14/22 at 9:02 am with Testing Personnel #3 revealed the laboratory uses the MyStaire Clean Prep dead air box for specimen processing. 3. A review of the laboratory's "iAMP COVID-19 Detection Kit" Instructions for Use (IFU) revealed a section titled "Specimens" stating, "Specimen processing should be performed in a certified class II biological safety cabinet following biosafety level 2 or higher guidelines." 4. A review of the laboratory's "CLEANPREPTM Dead Air Box Workstation Circulation-Free Enclosure" operator's manual revealed the dead air box was not designated as a class II biological safety cabinet. 5. A review of the laboratory's "Laboratory Director" policy revealed a section stating, "Ensure that the physical plant and environmental conditions are appropriate for testing performed and provide a safe workplace in which employees are protected from physical, chemical, and biological hazards. " 6.

	An interview on 4/14/22 at 11:52 am with the General Supervisor confirmed the laboratory did not use a biosafety cabinet type II when specimen sampling for iAMP COVID-19 Detection Kit testing.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: . A. Based on record review and interview with the General Supervisor, the Laboratory Director failed to ensure a quality control program was established for the QIAstat-Dx Respiratory SARS-CoV-2 Panel for 5 (November 2021 to April 2022) of 5 months the test system has been in use. Findings include: 1. A review of the laboratory's patient test records revealed the following patients received testing using the QIAstat-Dx Respiratory SARS-CoV-2 Panel: a. Patient RSP21-00066 tested on 11 /30/2021. b. Patient RSP21-00254 tested on 12/21/2021. c. Patient RSP22-00112 tested on 01/25/2021. d. Patient RSP22-00203 tested on 03/05/2022. 2. A review of the laboratory's "QIAstat-Dx Respiratory SARS-CoV-2 Panel Instructions for Use (Handbook)" revealed a section titled "Quality Control" stating, "External controls are not provided with the QIAstat-Dx Respiratory SARS-CoV-2 Panel. Quality control requirements should be performed in conformance with local, state, and/or federal regulations or accreditation requirements and your laboratory ' s standard quality control procedures." 3. A review of the laboratory's "Laboratory Director" policy revealed a section stating, "Ensure that quality control and quality assessment programs are established and maintained to monitor general, pre-analytic, analytic, and post-analytic laboratory activities in order to identify errors or potential problems that could lead to errors." 4. The surveyor requested documentation of external quality control testing performed for the dates listed above on 4/14/22 at 2:07 pm and it was not made available. 5. An interview on 4/14/22 at 2:22 pm with the GS confirmed the laboratory had not performed external quality control testing since the laboratory performed performance specification testing when the test system was initially installed. 6. A review of patient test records on the QIAstat-Dx Respiratory SARS-CoV-2 Panel instrument revealed a total of 47 patients had been tested without external quality control testing since 11/30/21. B. Based on record review and interview with Testing Personnel #3, the Laboratory Director failed to ensure quality control programs were maintained for the iAMP COVID-19 Detection Kit test system for 2 (Patients BLC21-14010 and BLC21-14465) of 15 patient testing dates reviewed. Findings include: 1. A review of patient test records revealed the following patients received testing via the iAMP COVID-19 Detection Kit test system: a. BLC21-14010 tested on 11/19/2021. b. BLC21-14465 tested on 11/21/2021. 2. A review of quality control records for 11/19/21 and 11/21/21 revealed a lack of documentation of quality control performed. 3. A review of the laboratory's "Laboratory Director" policy revealed a section stating, "Ensure that quality control and quality assessment programs are established and maintained to monitor general, pre-analytic, analytic, and post-analytic laboratory activities in order to identify errors or potential problems that could lead to errors." 4. A review of the laboratory's "iAMP COVID-19 Detection Kit" Instructions For Use (IFU) revealed a section titled "Assay Controls" stating, "Assay controls should be tested concurrently with all test samples in each instrumental run. PC - positive template control with an expected Ct value range,

	serves as a control for amplification and detection of SARS-CoV-2 RNA. NC - negative template control, serves to verify that analyte contamination does not occur during reaction setup." 5. An interview on 4/14/22 at 2:07 pm with Testing Personnel #3 confirmed the laboratory did not have quality control data for the runs with the patients listed above.
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: . Based on record review and interview with the General Supervisor, the Laboratory Director failed to ensure testing personnel had the appropriate training to accurately perform testing using the iAMP COVID-19 Detection Kit and the QIAstat-Dx Respiratory SARS-CoV-2 Panel test systems for 3 (Testing Personnel #1-#3) of 3 testing personnel performing patient testing. Findings include: 1. A review of the laboratory's "iAMP COVID-19 Detection Kit" Instructions for Use (IFU) revealed a section stating, "The iAMP COVID-19 Detection Kit is intended for use by qualified and trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time nucleic acid amplification and in vitro diagnostic procedures." 2. A review of the laboratory's "QIAstat-Dx Respiratory SARS-CoV-2 Panel Instructions for Use (Handbook)" revealed a section stating, "Testing with the QIAstat Dx Respiratory SARS-CoV-2 Panel is intended for use by qualified and trained operators who are proficient in performing the tests using the QIAstat Dx Analyzer System." 3. A review of the laboratory's personnel training and competency records revealed a lack of documentation of training or competency for the iAMP COVID-19 Detection Kit for Testing Personnel #1-#3 and a lack of documentation of training or competency for the QIAstat Dx Analyzer System for Testing Personnel #2. 4. An interview on 4/14/22 at 2:12 pm with the General Supervisor confirmed Testing Personnel #1-#3 had performed testing using the test systems listed above and did not have training available.
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 interview, the Technical Supervisor did not meet the qualification requirements of 493.1449. Findings include: 1. The laboratory failed to ensure the Technical Supervisor was qualified. See 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 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 (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 interview with the General Supervisor, the laboratory failed to ensure the Technical Supervisor was qualified for 1 of 1 Technical Supervisor listed on Form CMS-209. Findings include: 1. A review of the laboratory's personnel records revealed the Technical Supervisor listed on Form CMS-209 was hired in January 2021. 2. A review of the Technical Supervisor's qualifications revealed a lack of documentation showing their qualifications met the following requirements: a. 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. b. 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. 3. The surveyor requested the additional documentation showing the Technical Supervisor met the qualification requirements on 4/14/22 at 9:54 am and it was not made available. 4. An interview on 4/14/22 at 2:12 pm with the General Supervisor confirmed the laboratory did not have the qualification documentation to determine the Technical Supervisor was qualified. 5. The laboratory was given an additional 7 days after the survey to provide the additional qualification documentation and it was not received.