Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0969542	01/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Narayanan Pediatric Clinic	3964 Goodman Road, Suite 133, Southaven, MS	

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	CONDITIONS CITED: D6076 Laboratory Director D6108 Technical Supervisor D6168 Testing Personnel
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on the review of manufacturer's instructions for BD Veritor System Influenza A & B and SARS-CoV-2 testing, patients test count reports, observation of BD Veritor test cartridges and interview with testing personnel (TP) #1, the laboratory failed to perform Influenza A & B and SARS- CoV-2 testing following manufacturer's instructions for twenty-three of twenty-three months, with a total of 1615 patient tests performed and reported during this time frame. Findings include: 1. Review of BD Veritor manufacturer's instructions for the Influenza A & B and SARS-CoV-2 states under Interpretation of Results: "Test results must NOT be read visually. The BD Veritor System Reader (purchased separately) must be used for all interpretation of test results." 2. On 1/8/2025, the surveyor observed three boxes of BD Veritor test cartridges in use in the laboratory. There was no BD Veritor System reader observed in the laboratory to interpret Influenza A & B and SARS-CoV-2. 3. An interview with TP #1 on 1/8/2025 at 11:30 a.m., confirmed the laboratory had not used a BD Veritor System reader to interpret Influenza A & B or SARS-CoV-2 patient testing results from the last survey on 2/16/2023 until 1/8/2025. Between the dates, 945 Influenza A & B and 670 SARS-CoV-2 tests were performed on patients. 1615 out of 1615 patient BD tests were read and interpreted visually.

D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (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: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for the BD Veritor System for Influenza A & B and SARS-CoV-2 testing, surveyor observation of BD Veritor test cartridges, patient test count reports, and interview with Testing Personnel #1 and the Office Manager, the laboratory failed to establish performance specifications for performing BD Veritor System instrument. Findings include: 1. Review of manufacturers' instructions for the BD Veritor System for Influenza A & B and SARS-CoV-2 testing, states the tests results must not be read visually and must be determined using the BD Veritor System Instrument. The manufacturer's instructions also state, "Failure to follow the instructions or modification of the test system instructions will result in the test no longer meeting the requirements for waived category." 2. On 1/8/2025 the surveyor observation confirmed the laboratory had modified Influenza A & B and SARS-CoV-2 testing with the BD Veritor test cartridges by reading the test results visually without using a BD Veritor System instrument. 3. There was no documentation of the establishment of performance specifications for reading BD Veritor Influenza A & B test and SARS-CoV-2 cartridges visually without using a BD Veritor System Instrument to include accuracy, precision, analytical sensitivity, and analytical specificity. A total of 1615 tests were performed on Influenza A & B and SARS-CoV-2 between 2/16/2023 until 1/8/2025. 3. An interview with the TP #1 and the Office Manager on 1/8/2025 at 11:30 a.m., revealed the laboratory had modified Influenza A & B and SARS-CoV-2 testing with the BD Veritor test cartridges by reading the test results visually with using a BD Veritor System Instrument.
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 review of the CMS 209 personnel form, BD Veritor System manufacturer's instructions, documentation of personnel qualifications, observation of BD Veritor test cartridges and interview with Testing Personnel (TP #1) and the Office Manager, the laboratory director, listed on the CMS 209 personnel form, does not meet the qualification requirements of 493.1443 of this subpart for a laboratory performing

	high complexity testing. Findings include: Review of manufacturers' instructions for the BD Veritor System for Influenza A & B and SARS-CoV-2 testing, observation of BD Veritor test cartridges and interview with TP #1 and the Office Manager on 1/8 /2025 at 11:30 a.m., revealed the laboratory had modified Influenza A & B and SARS-CoV-2 testing with BD Veritor test cartridges by reading the test results visually without using a BD Veritor System Instrument. The manufacturer's instructions for the BD Veritor System for Influenza A & B and SARS-CoV-2 testing state "Test are not meant to be visually determined. All test results must be determined using the BD Veritor System Instrument. Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived category." A modified test is considered uncategorized by the FDA and therefore, becomes a high complexity test. Review of the personnel file of the laboratory director (LD), listed on the CMS 209 personnel form, revealed this individual does not meet the qualification requirements of 493.1443 of the subpart for a laboratory performing high complexity testing. Refer to 6078 (laboratory Director Qualifications)
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director 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 (b)(2)(i) Be a doctor of medicine, a 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 2 years of experience directing or supervising high complexity testing; and (b)(2)(iii) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(3)(i)(A) Hold an earned doctoral degree in a chemical, biological, clinical or medical laboratory science or medical technology from an accredited institution; or (b)(3)(i)(B) Hold an earned doctoral degree; and (b)(3)(i)(B)(1) Have at least 16 semester hours of doctoral level coursework in biology, chemistry, medical technology (MT), clinical laboratory science (CLS), or medical laboratory science (MLS); or (b)(3)(i)(B)(2) An approved thesis or research project in biology/chemistry/MT/CLS/MLS related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (b)(3)(ii) Be certified and continue to be certified by a board approved by HHS; and (b)(3)(iii) Have at least 2 years of: (b)(3)(iii)(A) Laboratory training or experience, or both; and (b)(3)(iii)(B) Laboratory experience directing or supervising high complexity testing; and (b)(3)(iv) Have at least 20 CE credit hours in laboratory practice that cover the director responsibilities defined in 493.1445; or (b)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a laboratory director of high complexity testing under this section if they were qualified and serving as a laboratory director of high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(5) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, or the American Osteopathic Board of

	Pathology. This STANDARD is not met as evidenced by: Based on review of the CMS 209 personnel form, BD Veritor System manufacturer's instructions, documentation of personnel qualifications, observation of BD Veritor test cartridges and interview with Testing Personnel (TP #1) and the Office Manager, the laboratory director, listed on the CMS 209 personnel form, does not meet the qualification requirements of 493.1443 of this subpart for a laboratory performing high complexity testing. Findings include: Review of manufacturers' instructions for the BD Veritor System for Influenza A & B and SARS-CoV-2 testing, observation of BD Veritor test cartridges and interview with TP #1 and the Office Manager on 1/8 /2025 at 11:30 a.m., revealed the laboratory had modified Influenza A & B and SARS-CoV-2 testing with BD Veritor test cartridges by reading the test results visually without using a BD Veritor System Instrument. The manufacturer's instructions for the BD Veritor System for Influenza A & B and SARS-CoV-2 testing state "Test are not meant to be visually determined. All test results must be determined using the BD Veritor System Instrument. Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived category." A modified test is considered uncategorized by the FDA and therefore, becomes a high complexity test. Review of the personnel file of the laboratory director (LD), listed on the CMS 209 personnel form, revealed this individual does not meet the qualification requirements of 493.1443 of the subpart for a laboratory performing high complexity testing.
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 review of the CMS 209 personnel form, BD Veritor manufacturer's instructions, documentation of personnel qualifications, observation of BD Veritor test Cartridges and interview with Testing Personnel (TP #1) and the Office Manager, the laboratory does not have technical supervisor who meets the qualification requirements of 493.1449 of this subpart for a laboratory performing high complexity testing. Findings include: Review of manufacturer's instructions for the BD Veritor System for Influenza A & B and SARS-CoV-2 testing, observation of BD Veritor test cartridges and interview with TP #1 and the Office Manager on 1/8/2025 at 11:30 a. m., revealed the laboratory had modified Influenza A & B and SARS-CoV-2 testing with BD Veritor test cartridges by reading the test results visually without using a BD Veritor System Instrument. The manufacturer's instructions for the BD Veritor System for Influenza A & B and SARS-CoV-2 testing state "Test results are not meant to be visually determined. All test results must be determined using the BD Veritor System Instrument. Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived category." A modified test is considered uncategorized by the FDA and therefore, becomes a high complexity test. Review of the laboratory's personnel files revealed that none of the individuals listed on the CMS 209 personnel form meet the qualification requirements for technical supervisor at 493.1449 of the subpart for a

	laboratory performing high complexity testing. Refer to D6111 (Technical Supervisor Qualifications)
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. (c) Bacteriology, Mycobacteriology, Mycology, Parasitology or Virology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, mycobacteriology, mycology, parasitology, or virology, 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 (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 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty; or (c)(3)(i)(A) Have an earned doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (c)(3)(i)(B) Meet the requirements in 493.1443(b)(3)(i)(B); 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)(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 of experience in high complexity testing within the applicable subspecialty; or (c)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (c)(4)(i)(B)(1) Meet bachelor's degree equivalency; and (c)(4)(i)(B)(2) Have at least 16 semester hours of additional graduate level coursework in chemical, biological, clinical or medical laboratory science, or medical technology; or (c)(4)(i)(C)(1) Meet bachelor's degree equivalency; and (c)(4)(i)(C)(2) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, or clinical or medical laboratory science coursework and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; 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 of experience in high complexity testing within the applicable subspecialty; or (c)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (c)(5)(i)(B) Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either- (c)(5)(i)(B)(1) 48 semester

hours of medical laboratory technology courses; or (c)(5)(i)(B)(2) 48 semester hours of science courses that include- (c)(5)(i)(B)(2)(i) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; (c)(5)(i)(B)(2)(ii) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and (c)(5)(i)(B)(2)(iii) 24 semester hours of chemistry, biology, or medical laboratory science or technology in any combination; 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 of experience in high complexity testing within the applicable subspecialty. (d) Diagnostic Immunology, Chemistry, Hematology, Radiobioassay, or Immunohematology - If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, chemistry, hematology, radiobioassay, or immunohematology, the individual functioning as the technical supervisor must- (d)(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 (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or (d)(3)(i)(A) Have an earned doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (d)(3)(i)(B) Meet the education requirement at 493.1443(b)(3)(i)(B); and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the applicable specialty; or (d)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (d)(4)(i)(B) Meet the education requirement at paragraphs (c)(4)(i)(B) or (C) of this section; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or (d)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (d)(5)(i)(B) Meet the education requirement at paragraph (c)(5)(i)(B) of this section; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty. (e) Cytology- 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- (e)(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 (e)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (e)(2) An individual qualified under paragraph (b) or (e)(1) of this section may delegate some of the cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraph (b) or (e)(1)(ii) of this section provided the technical supervisor qualified under paragraph (b) or (e)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met. (f) Histopathology - 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- (f)(1) Meet one of the following requirements: (f)(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 (f)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American

Osteopathic Board of Pathology; or (f)(1)(ii) An individual qualified under paragraph (b) or (f)(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 (f)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (f)(2) For tests in dermatopathology, meet one of the following requirements: (f)(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 (f)(2)(i)(B) Meet one of the following requirements: (f)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (f)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology; or (f)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology; or (f)(2)(ii) An individual qualified under paragraph (b) or (f)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (f)(3) For tests in ophthalmic pathology, meet one of the following requirements: (f)(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 (f)(3)(i)(B) Must meet one of the following requirements: (f)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (f)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (f)(3)(ii) An individual qualified under paragraph (b) or (f)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (g) Oral Pathology- 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: (g)(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 (g)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (g)(2) Be certified in oral pathology by the American Board of Oral Pathology; or (g)(3) An individual qualified under paragraph (b) or (g)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (g)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (h) Histocompatibility - If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either- (h)(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 (h)(1)(ii) Have training or experience that meets one of the following requirements: (h)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (h)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (h)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (h)(2)(i) Have an earned doctoral degree in a biological, clinical or medical laboratory science, or medical technology from an accredited institution; or meet the education requirement at 493.1443(b)(3)(i)(B); and (h)(2)(ii) Have training or experience that meets one of the following requirements: (h)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (h)(2)(ii)(B)(1) Have

	2 years of laboratory training or experience, or both, in the specialty of general immunology; and (h)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (i) Clinical cytogenetics- If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must- (i)(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 (i)(1)(ii) Have 4 years of laboratory training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (i)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, clinical or medical laboratory science, or medical technology from an accredited institution; or meet the education requirement at 493.1443(b)(3)(i)(B); and (i)(2)(ii) Have 4 years of laboratory training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (j) Notwithstanding any other provision of this section, an individual is considered qualified as a technical supervisor under this section if they were qualified and serving as a technical supervisor for high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. This STANDARD is not met as evidenced by: Based on review of the CMS 209 personnel form, BD Veritor System manufacturer's instructions, documentation of personnel qualifications, observation of BD Veritor test Cartridges and interview with Testing Personnel (TP #1) and the Office Manager, the laboratory does not have technical supervisor who meets the qualification requirements of 493.1449 of this subpart for a laboratory performing high complexity testing. Findings include: Review of manufacturer's instructions for the BD Veritor System for Influenza A & B and SARS CoV2 testing, observation of BD Veritor test cartridges and interview ith TP #1 and the Office Manager on 1/8/2025 at 11:30 a.m., revealed the laboratory had modified Influenza A & B and SARS CoV2 testing with BD Veritor test cartridges by reading the test results visually without using a BD Veritor System Instrument. The manufacturer's instructions for the BD Veritor System for Influenza A & B and SARS CoV2 testing state "Test results are not meant to be visually determined. All test results must be determined using the BD Veritor System Instrument. Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived category." A modified test is considered uncategorized by the FDA and therefore, becomes a high complexity test. Review of the laboratory's personnel files revealed that none of the individuals listed on the CMS 209 personnel form meet the qualification requirements for technical supervisor at 493.1449 of the subpart for a laboratory performing high complexity testing.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493.1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the CMS 209 personnel form, BD Veritor System manufacturer's instructions, observation of BD Veritor test cartridges, documentation of personnel qualifications and interview with Testing Personnel (TP #1) and the Office Manager,

	the testing personnel listed on the CMS 209 personnel, do not meet the qualification requirements of 493.1489 of this subpart for a laboratory performing high complexity testing. Findings include: Review of manufacturer's instructions for the BD Veritor System for Influenza A & B and SARS-CoV-2 testing, observation of BD Veritor test cartridges and interview with TP #1 and the Office Manager on 1/8/2025 at 11:30 a. m., revealed the laboratory had modified Influenza A & B and SARS-CoV-2 testing with BD Veritor test cartridges by reading the test results visually without using a BD Veritor System Instrument. The manufacturer's instructions for the BD Veritor System for Influenza A & B and SARS-CoV-2 testing state "Test results are not meant to be visually determined. All test results must be determined using the BD Veritor System Instrument. Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived category." A modified test is considered uncategorized by the FDA and therefore, becomes a high complexity test. Review of the laboratory's personnel files revealed that none of the individuals listed on the CMS 209 personnel form meet the qualification requirements for testing personnel at 493.1489 of this subpart for a laboratory performing high complexity testing. Refer to D6171 (Testing Personnel Qualifications)
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an

	accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the CMS 209 personnel form, BD Veritor System manufacturer's instructions, observation of BD Veritor test cartridges, documentation of personnel qualifications and interview with Testing Personnel (TP #1) and the Office Manager, the testing personnel listed on the CMS 209 personnel, do not meet the qualification requirements of 493.1489 of this subpart for a laboratory performing high complexity testing. Findings include: Review of manufacturer's instructions for the BD Veritor System for Influenza A & B and SARS-CoV-2 testing, observation of BD Veritor test cartridges and interview with TP #1 and the Office Manager on 1/8/2025 at 11:30 a. m., revealed the laboratory had modified Influenza A & B and SARS-CoV-2 testing with BD Veritor test cartridges by reading the test results visually without using a BD Veritor System Instrument. The manufacturer's instructions for the BD Veritor System for Influenza A & B and SARS-CoV-2 testing state "Test results are not meant to be visually determined. All test results must be determined using the BD Veritor System Instrument. Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived category." A modified test is considered uncategorized by the FDA and therefore, becomes a high complexity test. Review of the laboratory's personnel files revealed that none of the individuals listed on the CMS 209 personnel form meet the qualification requirements for testing personnel at 493.1489 of this subpart for a laboratory performing high complexity testing.