Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	36D0859172	06/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Saint Augustine Manor	7801 Detroit Avenue, Cleveland, OH	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record reviews and an interview with Testing Personnel (TP) #3, the Laboratory Director (LD) failed to attest to the routine integration of chemistry proficiency testing (PT) samples into the patient workload using the laboratory's methods for one out of one PT event in 2021. This deficient practice had the potential to affect 60 patients tested under the specialty of chemistry. Findings Include: 1. Review of the laboratory's policy and procedure signed and dated on 11/20/2017 by the previous LD, titled "Proficiency Testing", provided on the date of the inspection, found the following statement: " Procedure...9. Testing personnel and the medical director will sign the attestation sheet documenting that the samples were tested in the same manner as patient samples." 2. Review of the 2021 API chemistry core 1st event attestation statement page revealed TP#1 had signed the LD attestation. 3. The inspector requested the 2021 API chemistry core 1st event attestation statement page which contained the LD signature from TP#3. TP#3 was unable to provide the requested document and confirmed TP#1 had attested for the LD. The interview occurred 06/23/2021 at 12:15 PM.
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: Based on record reviews and interviews with Testing Personnel (TP) #1 and TP#3, the laboratory failed to successfully participate in a PT program for the non-waived pCO2, pH and pO2 testing performed under the specialty of routine chemistry. This deficient practice had the potential to affect 24 patients tested under the specialty of chemistry from 01/26/2021 to 06/23/2021. Findings Include: 1. Review of 2021 API PT documents revealed no 2nd event testing records. 2. The inspector requested the 2021 API 2nd event testing records from TP#1 and TP#3. TP#1 via a conference call confirmed the laboratory failed to submit PT for pCO2, pH and pO2 for 2021 2nd event testing which resulted in a subsequent unsuccessful analyte performance. TP#3 was unable to provide the requested documents as requested. The interviews occurred 06/23/2021 at 12:15 PM. pCO2: partial pressure carbon dioxide pH: potential of hydrogen pO2: partial pressure oxygen
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record reviews and an interview with Testing Personnel (TP) #3, the current Laboratory Director (LD) failed to ensure policies and procedures were approved, signed and dated before use. All patients tested under the subspecialty of chemistry from 01/07/2019 to 06/23/2021 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's policy and procedures provided on the date of the inspection revealed no current LD approval signature and date. 2. The inspector requested policies and procedures approved, signed and dated by the current LD from TP#3. 3. TP#3 confirmed all policies and procedures were not approved, signed and dated by the current LD before use. The interview occurred 06 /23/2021 at 2:30 PM.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform

	test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on record reviews and interviews with Testing Personnel (TP) #1 and TP#3, the Laboratory Director failed to ensure 2021 API 2nd event proficiency testing (PT) activities were conducted as required under subpart H of this part. This deficient practice had the potential to affect 24 patients tested under the specialty of chemistry from 01/26/2021 to 06/23/2021. Findings Include: 1. Review of the policy and procedure titled "Proficiency Testing" found the following statement: "Procedure...2. Proficiency testing samples will be performed tri-annually as designated by the provider." 2. Review of 2021 API core chemistry PT documents revealed no 2021 API 2nd event testing records. 3. The inspector requested the 2021 API 2nd event testing records for pCO2, pH and pO2 from TP#1 via conference call, and TP#3. 4. TP#1 via a conference call confirmed the laboratory failed to submit 2021 API 2nd event testing for pCO2, pH and pO2 which resulted in a subsequent unsuccessful analyte performance. The interviews occurred 06/23/2021 at 11:30 AM. pCO2: partial pressure carbon dioxide pH: potential of hydrogen pO2: partial pressure oxygen
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based upon record reviews and an interview with Testing Personnel (TP) #3, the Laboratory Director (LD) failed to specify the duties and responsibilities of each person listed on the Form CMS 209. This deficient practice had the potential to affect 60 patients tested under the specialty of chemistry. Findings include: 1. Review of the Form CMS 209 found two individuals listed as the Technical Consultant and 14 individuals listed as Testing Personnel. 2. Review of policies and procedures provided on the date of inspection failed to find evidence of the duties and responsibilities for the Technical Consultant and each Testing Personnel in writing by the laboratory director. 3. The inspector requested the approved, signed and dated duties and responsibilities for Technical Consultants and Testing Personnel from TP#3. TP#3 confirmed the LD failed to specify in writing the duties of all personnel listed on the Form CMS 209 and was unable to provide the requested document. The interview occurred 06/23/2021 at 10:55 AM.