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| <b>Statement of Deficiencies</b>   | <b>(X1) Provider/Supplier/CLIA Identification Number</b><br><br>36D0859172   | <b>(X3) Date Survey Completed</b><br><br>12/05/2022 |
| <b>Name of Provider or Supplier</b><br><br>Saint Augustine Manor   | <b>Street Address, City, State</b><br><br>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. |  |   |

| <b>(X4) ID Prefix Tag</b> | <b>Summary Statement of Deficiencies</b>  |
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| <b>D6000</b>              | <p>MODERATE COMPLEXITY LABORATORY DIRECTOR<br/>CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by:<br/>Based on record review and an interview with Testing Personnel (TP) #1, the Laboratory Director failed to provide overall management and direction in accordance with 493.1407 of this subpart in the specialty of Chemistry. 131 out of 131 patient arterial blood gas (ABG) testing procedures performed in this laboratory from 07/13 /2021 to 12/05/2022 had the potential to be affected by this deficient practice. Findings Include: 1. The Laboratory Director failed to delegate the Technical Consultant (TC) responsibilities to a qualified individual for the arterial blood gas (ABG) testing conducted in the subspecialty of Routine Chemistry. (Refer to D6004) 2. The Laboratory Director failed to employ an individual functioning in the role of a Technical Consultant (TC), who possessed the appropriate education to perform the TC responsibilities described in subpart M. (Refer to D6028)</p> |
| <b>D6004</b>              | <p>LABORATORY DIRECTOR RESPONSIBILITIES<br/>CFR(s): 493.1407(a)(b)</p> <p>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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If</p>   |

the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Office Manager (OM), the Laboratory Director failed to delegate the Technical Consultant (TC) responsibilities to a qualified individual for the arterial blood gas (ABG) testing conducted in the subspecialty of Routine Chemistry. This deficient practice had the potential to affect 131 out of 131 patient ABG tests that were conducted between 07/13/2021 to 12/05/2022. Findings Include: 1. Review of the Laboratory Director's TC delegation letter to TP#1, provided for the inspection, found that the Laboratory Director did not delegate to a qualified individual. TP#1 had achieved an Associate of Applied Science in Respiratory Care and did not meet the TC qualification requirements. 2. Review of the laboratory's 2021 and 2022 competency assessment documentation, provided for the inspection, revealed TP#1, TP#2, TP#3, and an individual not listed on the CMS-209 conducted TP competency assessments for nine out of nine TP. 3. Review of the laboratory's 2021 and 2022 quality control and quality assessment documentation provided for the inspection, did not find any indication of the listed TC initials or signatures for any review activities. 4. The OM confirmed on 12/05/2022 at 11:45 AM and again on 12/14/2022 at 2:05 PM via a telephone conversation that the Laboratory Director delegated TC responsibilities to TP#1 and listed another individual as the TC on the CMS-209.

**D6028**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(10)

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)(10) 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 review of the laboratory's Form CMS-209, competency assessment documentation and education records, the Laboratory Director failed to employ an individual functioning in the role of a Technical Consultant (TC), who possessed the appropriate education to perform the TC responsibilities described in subpart M. This deficient practice had the potential to affect 131 out of 131 patient arterial blood gas (ABG) tests that were conducted between 07/13/2021 to 12/05/2022. Findings Include: 1. Review of the laboratory's Form CMS-209, signed by the Laboratory Director on 11/18/2022, listed and credentialed one individual as the sole TC. 2. Review of the laboratory's 2021 and 2022 competency assessment documentation, found annual assessment records for all testing personnel (TP). The records indicated that the TP were assessed by TP#1, TP#2, TP#3, or an individual not listed on the CMS-209 and not by the listed and credentialed TC. 3. Review of the Laboratory Director's delegation of responsibility letter to TP#1 and the highest level of education by degree/diploma for TP#1 revealed that TP#1 was delegated TC responsibilities by the Laboratory Director, had achieved an Associate of Applied Science in Respiratory

Care and did not meet the moderate complexity TC qualification requirements. Additionally, the Laboratory Director did not delegate TC responsibilities to the listed and credentialed TC on the CMS-209.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Office Manager (OM), the Technical Consultant (TC) failed to evaluate and document the competency of nine out of nine Testing Personnel (TP) in 2021 and 2022 assuring their competency was maintained in order to perform moderately complex arterial blood gas (ABG) testing in the subspecialty of Routine Chemistry and report the test results promptly, accurately, and proficiently. 131 out of 131 patient ABG tests conducted by TP#1, TP#2, TP#3, TP#4, TP#5, TP#6, TP#7, TP#8, and TP#9 from 07/13/2021 to 12/05/2022 had the potential to be affected by this deficient practice. Findings Include: 1. Review of the laboratory's "Technical Consultant Responsibilities", provided for the inspection, found the following: "Ensures personnel have been appropriately trained and demonstrates competency prior to testing patient specimens." "Policy & Procedure established for monitoring personnel competencies." "Continuing education needs are identified, and training provided." 2. Review of the laboratory's Form CMS-209, approved via signature and date by the Laboratory Director on 11/18/2022, found one individual listed and credentialed by the Laboratory Director as a TC. 3. Review of the laboratory's competency assessment documentation provided for the inspection identified the following dates and individuals who performed TP competency assessments: TP initial 6 month 12 month annual 1 8/21-LD 2/22-TP3 8/22-\* n/a 2 7/22-TP1 3 10/22-TP1 4 8/22-TP1 5 9/22-TP1 6 10/22-TP1 7 9/22-TP1 8 8/22-TP1 9 10/22-TP1 \* 7/21-TP2 1/22-TP1 8/22-TP1 n/a LD; Laboratory Director n/a; not applicable \*; by an individual not listed on the CMS-209 4. Review of the "Laboratory Director Responsibilities Delegation", approved by the Laboratory Director on 08/03/2022, provided for the inspection, found that the Laboratory Director delegated TC responsibilities to TP#1 who had achieved an Associates of Applied Science in Respiratory Care and does not meet the TC regulatory qualification requirements. 5. Review of the laboratory's 2021 and 2022 competency assessment records did not find that any of the nine TP had their competency assessed by the only listed and credentialed TC. The Inspector requested the 2021 and 2022 competency assessment documentation as assessed by the sole TC for TP#1, TP#2, TP#3, TP#4, TP#5, TP#6, TP#7, TP#8, and TP#9 from TP#1. TP#1 confirmed, via a telephone conversation on 12/14/2022 at 2:05 PM, that the TC did not conduct any of the 2021 and 2022 TP competency assessments and was unable to provide the requested documentation on the date of or within seven days after the onsite inspection.