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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 33D0956796 | (X3) Date Survey Completed 07/25/2019 |
| Name of Provider or Supplier Gregory J Healey Md | Street Address, City, State 25 Park Street, Canton, NY | |
| 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 |
|---------------------------|---|
| D5209 | <p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the competency assessment policy and competency assessments for six testing personnel and an interview with two of the laboratory testing personnel, the laboratory failed to follow its polices and procedures for documenting the competency of five of six testing personnel. FINDINGS: The two laboratory testing personnel confirmed on July 25, 2019 at approximately 11:00 AM, that five of six testing personnel did not have an annual evaluation performed in the calendar year 2018. The six testing person was hired on July 1, 2019 and is currently training in the laboratory for hematology and waived testing.</p> |
| D5291 | <p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on a surveyor's review of the laboratory's Quality Assurance (QA) policy and</p> |

confirmed in an interview with the two laboratory testing personnel, the laboratory failed to follow their established written QA policy and perform an annual QA review, as required by the laboratory's QA policy, for the calendar year 2018.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's QA policy and confirmed during the interview with the two testing personnel, the laboratory director failed to ensure that the laboratory's quality assessment (QA) policy/procedure was followed. Refer to: D5291

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on a surveyor's review of the personnel files and confirmed in an interview with the two laboratory testing personnel, the laboratory director, acting as the technical consultant, failed to perform annual competency evaluation for five of six testing persons in calendar year 2018. Refer to D5209.