

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0856333	(X3) Date Survey Completed 11/07/2019
Name of Provider or Supplier Access Health Center	Street Address, City, State 1700 75th St, Downers Grove, IL	
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
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records, and interview with a laboratory representative; the laboratory failed to perform and document tachometer checks at least two times each year, as outlined by the manufacturer for the Clay Adams Sero-Fuge 2002 centrifuge used for immunohematology testing in 2017 through 2019. Findings Include: 1. Direct observation of the laboratory on 11-7-2019 at 9:05 am identified a Clay Adams Sero-Fuge 2002 centrifuge (Serial Number: 4120016) used for immunohematology Rhesus factor (Rh) testing. 2. Review of the manufacturer's operator's manual for the Sero-Fuge 2002 centrifuge stated, on page 20, that centrifuge should be check at least twice annually with an accurate photo electric tachometer. 3. Review of the laboratory's preventative maintenance records revealed the laboratory failed to check the Clay Adams Sero-Fuge 2002 centrifuge two time each year in 2017, 2018, and 2019. The centrifuge speed was checked on 03-29-2017 and 10-25-2019. 4. Review of the laboratory's Rh testing records found the laboratory performed 2,018 tests for Rh in 2018 through 2019. 5. On survey date 11-07-2019, at 11:45 am, the surveyor's findings were confirmed by the laboratory representative.</p>
D6021	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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</p>

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 review of laboratory records and interview with a laboratory representative; the laboratory director (LD) failed to ensure the quality assessment plan was maintained from 2017 through 2019. Findings Include: 1. Review of the laboratory policy and procedure manual identified the document, "Quality Assurance Program Components", which outlined the 10 components that will be reviewed and documented on the review worksheet quarterly each year. 2. Review of quality assurance documentation revealed the laboratory only performed and documented quality assurance reviews annually in 2017 through 2019. 2017 - Completed 09-01-2017 2018 - Completed 05-24-2018 2019 - Completed 10-25-2019 3. Review of the laboratory's Rh testing records found the laboratory performed 2,018 tests for Rh in 2018 through 2019. 4. On survey date 11-07-2019, at 11:45 am, the laboratory representative confirmed quarterly quality assurance reviews were not documented as described in the quality assurance plan in 2017 through 2019.