

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0650725	(X3) Date Survey Completed 10/17/2019
Name of Provider or Supplier Sickle Cell Disease Assoc Of America,	Street Address, City, State 18516 James Couzens Hwy, Detroit, MI	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with Testing Personnel #2 (TP2), the laboratory failed to document the proficiency testing attestation statement for 2 (first and second event of 2019) of 4 testing events reviewed. Findings include: 1. A record review of the College of American Pathologists' proficiency testing records revealed a lack of a documented attestation statement for the following testing events in 2019: a. HG-A b. HG-B 2. An interview on 10/17/19 at 11:40 am with TP2 confirmed the above testing events did not have a documented attestation statement.</p>
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by:</p>

	<p>. Based on record review and interview with Testing Personnel #2 (TP2), the laboratory failed to retain final proficiency testing reports for 1 (first event of 2018) of 4 testing events reviewed. Findings include: 1. A record review of the College of American Pathologists' proficiency testing records revealed a lack of final testing reports for the first testing event of 2018. 2. An interview on 10/17/19 at 12:12 pm with TP2 confirmed the final proficiency testing reports for the first event of 2018 had not been retained.</p>
<p>D5209</p>	<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 record review and interview with Testing Personnel #2 (TP2), the laboratory failed to assess annual testing personnel competency for Testing Personnel #1 for 1 (2019) of 2 years reviewed. Findings include: 1. A record review of laboratory personnel competency records revealed the last documented competency assessment for Testing Personnel #1 was in May 2018. 2. An interview on 10/17/19 at 11:05 am with TP2 confirmed Testing Personnel #1 did not have a documented competency assessment for 2019.</p>
<p>D5417</p>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.</p> <p>This STANDARD is not met as evidenced by: . Based on observation and interview with Testing Personnel #2 (TP2), the laboratory used expired SickleDex solubility buffer for the current lot in use. Findings include: 1. An observation made by the surveyor on 10/17/19 at 12:25 pm revealed a bottle of SickleDex solubility buffer, used in hemaglobinopathy screening tests, had an expiration date of 6/4/19. 2. A record review of patient logs revealed the following patients had testing performed after the buffer was expired: a. Patient #216065 tested on 8/15/19 b. Patient # 216098 tested on 9/25/19 3. An interview on 10/17/19 at 12:55 pm with TP2 confirmed the bottle of SickleDex solubility buffer was expired and was in use by the laboratory.</p>
<p>D6091</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii)</p> <p>The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.</p> <p>This STANDARD is not met as evidenced by:</p>

. Based on record review and interview with Testing Personnel #2 (TP2), the laboratory director failed to ensure proficiency testing reports were reviewed by testing personnel for 1 (first event of 2019) of 4 events reviewed. Findings include: 1. A record review of the College of American Pathologists' proficiency testing records revealed a lack of testing personnel review for the first event of 2019. 2. An interview on 10/17/19 at 11:40 am with TP2 confirmed there was no documented review of proficiency testing by testing personnel.

D6102

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(12)

The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
. Based on record review and interview with Testing Personnel #2 (TP2), the laboratory director failed to ensure all personnel have the appropriate training for the laboratory testing performed for 1 (TP2) of 2 testing personnel. Findings include: 1. A record review of laboratory training and competency records revealed a lack of documentation available for TP2 with the employment date of 9/26/19. 2. An interview on 10/17/19 at 11:05 am with TP2 confirmed training had not been documented.