

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0477913	(X3) Date Survey Completed 04/10/2019
Name of Provider or Supplier Sparks Clinic	Street Address, City, State 103 N First Street, Rockwall, TX	
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	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on review of American Proficiency Institute (API) proficiency testing documentation for 2017 and staff interview, the laboratory director failed to attest to the routine inegration of samples into the patient workload using the laboratory's routine methods. Findings: 1. Review of API proficiency testing documents revealed that attestation forms for the first, second and third events of 2017 had not been signed by the laboratory director, who also serves as the laboratory technical consultant (CMS form 209). 2. In an interview at the site on 04-10-2019, testing person 4 (CMS form 209) stated that the staff member previously responsible for maintenance of API records had left the facility, and she was unaware that the forms had been left unsigned. .</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: . Based on review of laboratory procedures for hematology and staff interview, the</p>

laboratory failed to provide a current procedure manual for hematology testing using the Sysmex XN-330 analyzer. Findings: 1. Laboratory procedures were reviewed. Included were a policy regarding daily controls and maintenance on the "Sysmex" dated 01-2013 and a policy on instrument flags for hematology dated 03-01-2015. Both policies predated the installation of the XN-330 analyzer. 2. In an interview at the site on 04-10-2019, testing person 4 stated that the staff was using the operator's manual provided by the manufacturer in lieu of a written laboratory procedure. .

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE
CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
. Based on review of method verification documentation for the Sysmex XN-330 hematology analyzer and staff interview, the laboratory failed to verify that the manufacturer's reference intervals were appropriate for the facility's patient population. Findings: 1. Method verification documentation for the Sysmex XN-330 hematology analyzer was reviewed. In studies provided principally by the manufacturer's field service representative, accuracy, precision and reportable range were addressed. 2. No evidence of reference range verification was included. In an interview at the site on 04-10-2019, testing person 4 stated she was not aware that the laboratory was responsible for performing such a study. 3. The documentation provided did not include evidence of review by the laboratory director/technical consultant (CMS form 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 review of testing personnel competency verification documentation for 2017, 2018 and 2019, confirmed by staff interview, the laboratory technical consultant failed to evaluate the competency of staff responsible for patient testing according to applicable regulations. Findings: 1. Documentation for testing person 1 (CMS form 209) consisted of sheets dated 11-21-17 and 11-21-18 titled "Laboratory Personnel Yearly Competency" marked "Pass" and signed by the laboratory director, who also serves as technical consultant (CMS form 209). No indication of methods employed to verify competency was included. 2. Documentation for testing person 2 (CMS form 209) consisted of a sheet dated 10-01-2018 titled "Laboratory Personnel Evaluation" consisting of a checklist including the required elements for competency verification. No documentation for 2017 was offered or could be made available. 3.

Documentation for testing person 3 (CMS form 209) consisted of a sheet dated 03-26-2018 titled "Laboratory Personnel Evaluation" consisting of a checklist including the required elements for competency verification. No documentation for 2017 was offered or could be made available. 4. Documentation for testing person 5 (CMS form 209) consisted of a sheet titled "Laboratory Personnel 6 Month Training" that read: "I have directly observed (testing person 5-name redacted) after 6 months and found him /her to be proficient in all areas of testing or have successfully completed a proficiency kit. She does not require direct supervision to perform or report test results." The sheet was signed by the laboratory director/technical consultant and dated 05-01-2018. 5. In an interview at the site on 04-10-2019, testing person 3, who also serves as the clinic manager, confirmed that the documentation presented was all that was available for verification of testing personnel competency. .

D6047

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(i)

The procedures for evaluation of the competency of the staff must include, but are not limited to direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing.

This STANDARD is not met as evidenced by:
. Based on review of testing personnel competency verification documentation for 2017, 2018 and 2019, confirmed by staff interview, the laboratory technical consultant failed to document evaluation of the competency of staff responsible for patient testing by direct observation of routine patient test performance. 1. Refer to D6046 (1) and (5). 2. Refer to D6046 (4) and (5). The document provided does not specify the method utilized. .

D6048

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(ii)

The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results.

This STANDARD is not met as evidenced by:
. Based on review of testing personnel competency verification documentation for 2017, 2018 and 2019, confirmed by staff interview, the laboratory technical consultant failed to evaluate the competency of staff responsible for patient testing by monitoring the recording and reporting of test results. 1. Refer to D6046 (1) and (5). 2. Refer to D6046 (4) and (5). The document provided does not specify the method utilized. .

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:
. Based on review of testing personnel competency verification documentation for

	<p>2017, 2018 and 2019, confirmed by staff interview, the laboratory technical consultant failed to document evaluation of the competency of staff responsible for patient testing by review of intermediate test results or worksheets, quality control records proficiency testing results and maintenance records. 1. Refer to D6046 (1) and (5). 2. Refer to D6046 (4) and (5). The document provided does not specify the methods utilized. .</p>
D6050	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks.</p> <p>This STANDARD is not met as evidenced by: . Based on review of testing personnel competency verification documentation for 2017, 2018 and 2019, confirmed by staff interview, the laboratory technical consultant failed to document evaluation of the competency of staff responsible for patient testing by direct observation of performance of instrument maintenance and function checks. 1. Refer to D6046 (1) and (5). 2. Refer to D6046 (4) and (5). .</p>
D6051	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.</p> <p>This STANDARD is not met as evidenced by: . Based on review of testing personnel competency verification documentation for 2017, 2018 and 2019, confirmed by staff interview, the laboratory technical consultant failed to document evaluation of the competency of staff responsible for patient testing through testing previously analyzed specimens, internal blind testing samples or proficiency testing samples. 1. Refer to D6046 (1) and (5). 2. Refer to D6046 (4) and (5). The document offered does not specify the method used. .</p>
D6052	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(vi)</p> <p>The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of problem solving skills.</p> <p>This STANDARD is not met as evidenced by: . Based on review of testing personnel competency verification documentation for 2017, 2018 and 2019, confirmed by staff interview, the laboratory technical consultant failed to document evaluation of the competency of staff responsible for patient testing by assessment of problem solving skills. 1. Refer to D6046 (1) and (5). 2. Refer to D6046 (4) and (5). The document provided does not specify the method utilized. .</p>

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 review of testing personnel competency verification documentation for 2017, 2018 and 2019, confirmed by staff interview, the laboratory technical consultant failed to evaluate the competency of staff responsible for moderate complexity patient testing at least annually after the first year. 1. Refer to D6046 (2) and (5). No documentation of competency verification was offered for 2017. 2. Refer to D6046 (3) and (5). No documentation of competency verification was offered for 2017. .

D6055

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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results.

This STANDARD is not met as evidenced by:

. Based on review of testing personnel training documentation for 2018 and 2019, method verification documentation for the Sysmex XN-330 hematology analyzer and staff interview, the laboratory director/technical consultant failed to reevaluate the performance of testing staff following a change in test methodology. Findings: 1. During review of survey documents as part of the entrance interview on 04-10-2019, it was revealed that the laboratory had replaced its hematology analyzer the previous month; the new instrument, a Sysmex XN-330, was put in service 03-07-2019. 2. Training documentation for laboratory testing staff was reviewed. Documents for testing person 1 did not include mention of specific training or performance evaluation for the new instrument. 3. Documents for testing person 2 included a sheet titled "Laboratory Personnel Training Checklist" specific for CBC (complete blood count) dated 10-01-2018, signed by testing person 4, and a sheet titled "Test Authorization" indicating approval to perform laboratory testing including CBC, signed by the laboratory director and dated 10-01-2018. All documentation predated introduction of the new instrument. 4. Documents for testing person 3 included a sheet titled "Laboratory Personnel Training Checklist" specific for CBC (complete blood count) dated 03-26-2018, signed by testing person 4, and a sheet titled "Test Authorization" indicating approval to perform laboratory testing including CBC, signed by the laboratory director and dated 03-26-2018. All documentation predated introduction of the new instrument. 5. Documents for testing person 4 included a sheet titled "Laboratory Personnel Training Checklist" specific for CBC (complete blood count) dated 10-01-2018, signed by testing person 2, and a sheet titled "Test Authorization" indicating approval to perform laboratory testing including CBC, signed by the laboratory director and dated 10-01-2018. All documentation predated introduction of the new instrument. 6. In an interview at the site on 04-10-2019, testing person 4 stated that staff had been trained in operation of the new instrument

during installation and validation, but no supporting documentation or evidence of personnel performance evaluation could be offered. .