

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 06D1100435	(X3) Date Survey Completed 06/07/2018
Name of Provider or Supplier Quicksilver Scientific Inc	Street Address, City, State 1960 Cherry Street, Louisville, CO	
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
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 a review of the quality assessment (QA) plan, a lack of customer service records, and laboratory director interview, the laboratory failed in 2018 to follow their written procedure to investigate, document, and resolve customer complaints after receiving a complaint regarding the accuracy of the laboratory's reference ranges on patient test reports in April 2018. Findings include: a. On 5-31-18, the Colorado CLIA program received a complaint from a customer of Quicksilver Scientific stating there could be a reporting problem with Lithium at Quicksilver Scientific. b. On 6-5-18 and 6-7-18, the Colorado CLIA program conducted an onsite complaint investigation at Quicksilver Scientific. c. During the survey on 6-5-18 at about 11 a.m., the laboratory director stated he remembered a customer complaint was received by the laboratory a few months earlier and he had discussed the problem with the complainant, but he was unsure whether the problem had been resolved. d. The QA Plan states, "Complaints are documented by the employee receiving the complaint. The documentation may take the form of a Corrective Action Report. The Laboratory Director and affected management are informed of all client complaints and assist in resolving the complaint." e. The laboratory could not find any record of the customer complaint during the surveys conducted on 6-5-18 and 6-7-18. f. The laboratory director confirmed no documentation existed of the complaint the laboratory received in April 2018 from the complainant and confirmed the laboratory failed to investigate, document, and resolve complaints as required by their QA plan.</p>

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on a review of the analyte verification records from 2015, patient test reports, and staff interview, the laboratory director failed to review and sign his approval of the verification data of 15 analytes before testing patient specimens using the inductively-coupled plasma-mass spectrometry (ICP-MS) analyzer. Findings include:

- a. The laboratory tested patient specimens only for mercury levels from the day testing began in February 2010 until 11-24-15.
- b. Surveyor notes from the 10-25-11, 1-29-14 and 1-27-16 surveys indicated the laboratory was only performing mercury testing.
- c. On page 2-B of the CMS-116 CLIA application from the survey conducted on 1-27-16 indicated the laboratory was only performing mercury testing.
- d. The CMS-116 CLIA application from the survey conducted on 2-15-18 did not indicate which analytes the laboratory was testing.
- e. During the survey on 6-7-18, testing personnel stated that the laboratory began testing patient specimens on 11-25-15 for 15 additional analytes (antimony, arsenic, cadmium, calcium, cobalt, copper, lead, lithium, magnesium, manganese, molybdenum, selenium, silver, strontium, and zinc).
- f. During the survey on 6-5-18 at around 11 a.m., the laboratory director stated he did not have any documentation to show the verification data for the 15 additional analytes had been reviewed and approved by him before the testing of patient specimens began on 11-25-15.
- g. On page 2-B of the CMS-116 CLIA application from the complaint survey conducted on 6-7-18 indicated the laboratory was testing for a total of 16 analytes: (antimony, arsenic, cadmium, calcium, cobalt, copper, lead, lithium, magnesium, manganese, mercury, molybdenum, selenium, silver, strontium, and zinc).
- h. During the survey on 6-7-18, the verification records that documented the performance of the additional 15 analytes in October 2015, showed the laboratory director had signed and dated the verification records on 6-7-18.
- i. During the survey on 6-5-18, the laboratory director confirmed he had failed to sign and date his review of the verification data of the additional 15 analytes when the laboratory completed the verification studies using the ICP-MS in October 2015.