

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2013239	(X3) Date Survey Completed 02/12/2021
Name of Provider or Supplier Quest Diagnostics Austin Rrl	Street Address, City, State 3708 Jefferson Street Suite B, Austin, 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
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: Review of 2019 College of American Pathologists (CAP) proficiency testing records and interview of facility personnel found that the laboratory failed to retain records for one of three proficiency testing events in Hematology testing for at least two years. The findings included: 1. Review of the College of American Pathologists (CAP) 2019 proficiency testing records for Hematology found that the laboratory failed to retain results for the FH13-C 2019 Hematology Auto Differentials, FH13 testing event. The laboratory failed to retain the original test records, attestation statements, and instrument test records for this event. 2. Proficiency testing records were requested but not provided. 3. Interview of testing person two on the CMS report 209 Laboratory Personnel Report conducted on February 2, 2021 at 2:25 PM confirmed that proficiency testing records for this event were not retained.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the College of American Pathologists (CAP) proficiency testing records from 2019 and staff interview, the laboratory failed to review and evaluate proficiency testing results for one of three hematology testing events. The findings included: 1. Review of CAP proficiency testing records from 2019 (3 testing events</p>

annually) found no documentation of review for the FH13-C 2019 Hematology Auto Differentials, FH13 testing event. 2. Interview of testing person two on the CMS report 209 Laboratory Personnel Report conducted on February 2, 2021 at 2:25 PM confirmed that proficiency testing records for this event were not retained.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:

Based on review of proficiency testing records, patient test records, and interview, the laboratory failed to participate in proficiency testing for quantitative serum Human Chorionic Gonadotropin (hCG) tested on the Dade Dimension Xpand for 1 of 6 events reviewed and received a false score of 100%. Findings follow. Review of the College of American Pathologists Survey Result Form from the first event of 2020, C-A General Chemistry, showed the laboratory did not participate in the testing event and submitted exception code 11 (unable to analyze) on 3/26/2020. Documentation showed proficiency samples were received on 3/10/2020, and due on 4/07/2020. Review of patient testing records from 3/10/2020 - 4/07/2020 showed 67 patients were reported. Interview with Technical Consultant #1, listed on the CMS form 209, on February 2, 2021 at 1455 in the laboratory confirmed the laboratory did not participate in the event for hCG on the Dimension and received a false score of 100% and continued to test patients at that time.