

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0700053	(X3) Date Survey Completed 10/16/2019
Name of Provider or Supplier Quest Diagnostics	Street Address, City, State 2291 W March Ln Ste 145f, Stockton, CA	
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
D5793	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory 2017 - 2018 proficiency testing records, the lack of documents, and interview with a Technical Supervisor for Hematology, it was determined that the laboratory failed to document all analytic systems corrective actions and include reviews for effectiveness. Findings included: a. Laboratory records titled "Survey Error Investigation and Corrective Action Report" documented Testing Personnel errors in Blood Cell Identification for two consecutive events and follow up activities, as follows: 1) Event: C/ 2017 Specimen: BCP-30 Lab reported: Lymphocyte Intended: Malignant Lymphoid Cell Follow up: Attend photomicrograph training 12/13/17; and perform 20 slides assessment in house training yearly requirement. Testing Personnel Review: 11/21/17 Technical Supervisor Review: 11/21/17 2) Event: A/ 2018 Specimen: BCP-09 Lab reported: Reactive Lymphocyte Intended: Malignant Lymphoid Cell Follow up: Will attend future photomicrograph assessment; and perform 20 slides assessment in house training. Testing Personnel Review: 3/22/18 Technical Supervisor Review: 3/23/18 b. The laboratory failed to provide for review documents for the required attendance at the photomicrograph reviews on 12/13/17 and in 2018; the 20 slides assessments in 2018 for both testing persons; and reviews of the effectiveness of corrective actions taken for each. And thus, the ability of testing personnel to identify Malignant Lymphoid Cells on manual microscopic analyses of blood smears could not be assured. c. Technical Supervisor-1 for Hematology affirmed (10/16/19 at 6pm) the aforementioned missing documents</p>

for completion of corrective actions and reviews for effectiveness. d. This deficiency was previously cited in 2017.

D6092

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on the lack of laboratory records and deficiency cited, the Laboratory Director is herein cited for deficient practice in ensuring that approved corrective actions were followed when proficiency testing results were found to be unacceptable or unsatisfactory. See D5793.

D6118

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(5)

The technical supervisor is responsible for resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications.

This STANDARD is not met as evidenced by:

Based on the lack of laboratory records and deficiency cited, the Technical Consultants are herein cited for deficient practice in ensuring that specified remedial actions are completed and documented. See D5793.