

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0670381	(X3) Date Survey Completed 10/16/2025
Name of Provider or Supplier Quest Diagnostics	Street Address, City, State 2999 Regent St Ste #101, Berkeley, 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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: . Based on observation of the laboratory analyzers: Chemistry/Endocrinology: Dimension EXL 200 (s/n DR273026), Hematology: Sysmex XS1000Ic (s/n A1135), Coagulation: Siemens CA620 (s/n 23329), and Microscope -- Nikon Eclipse E400 (s/n 664317); review of laboratory records for Testing Personnel, routine testing, and proficiency testing; and interview with Technical Consultant-1 (Technical Supervisor-1/General Supervisor-1/Testing Person-1), it was determined that the laboratory failed to include proficiency samples with the laboratory's regular patient workload for routine testing. Findings included: a. The laboratory's CMS209 Personnel Report (CLIA), 9/29/25, documented three Testing Persons routinely testing in Chemistry, Urinalysis, Endocrinology, and Hematology. b. Laboratory records for Proficiency testing documented Testing Personnel (TP) for each Event, as follows: Event Date Testing Person ----- 1. Chemistry 2022, A 3/09/22 1 " B 6/02/22 1 " C 9/27/22 1 2024, A 3/11/24 1 " B 6/10/24 1 " C 9/11/24 1 2025, A 3/05/25 1 2. Coagulation 2022, A 1/25/22 1 " B 5/11/22 1 " C 9/13/22 1 2024, B 5/09/24 3 " C 11/01/24 3 2025, A 2/27/25 3 3. Sed Rate 2023, B 11/14/23 1 2024, A 5/14/24 1 " B 11/13/24 1 2025, A 5/14/25 1 c. Laboratory test records documented Testing Persons performing routine testing on the same dates as proficiency testing, as follows: 1. Chemistry: Date Testing Persons ----- 3/09/22 1, 3 6/02/22 3, 4 9/27/22 4 3/11/24 3, 4 6/10/24 3 9/11/24 3, 1 2. Coagulation: Date Testing Persons ----- 1/25/22 3 5/11/22 1, 3 9/13/22 3 5/09/24 1, 3 11/01/24 3 2/27/25 1, 3 d. Technical Consultant-1/Testing Person-1 affirmed (10/02/25</p>

at 1:00 PM) the aforementioned findings; and thus, it was determined that proficiency samples weren't integrated into the routine patients testing process. e. The reliability and quality of routine test results reported by Testing Person-3 and Testing Person-4 for Chemistry/Endocrinology, and Testing Person-1 for Coagulation could not be assured during this Survey. The laboratory reported annual test volumes, as follows (CMS116 CLIA Application, 10/02/25): Chemistry, Urinalysis, Endocrinology = 40,226 Hematology, Coag = 25, 183 .

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

(e)(11) 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 review of laboratory records for personnel and Training, the lack of raw data and instrument printout records, and interview with laboratory personnel, the Laboratory Director is herein cited for deficient practice in ensuring that trainees demonstrated testing and obtained reliable, accurate, and reportable results. Findings included: a. The Laboratory Personnel Report (CLIA) [CMS209, 9/29/25] included three Testing Persons. b. Laboratory records for Testing Person-2 training on the Chemistry analyzer Dimension on 9/09/24 with initial evaluation on 10/04/24 failed to have attachments of raw data/instrument printouts of results. c. Technical Consultant-1 and Technical Consultant-2 affirmed the aforementioned training record and the laboratory policy that failed to require attaching raw data/ instrument printouts to authenticate the testing demonstration and ability to provide reliable results that are reportable and accurate. d. The quality and authenticity of training and initial evaluations for testing personnel could not be assured during this Survey. e. Three testing personnel routinely utilized six laboratory instruments (Siemens Dimension, Siemens Sysmex XS1000 Ic, Siemens CA620, Elitek Group Excyte 20, Siemens Cliniitek Status, Nikon Eclipse E400 microscope) to perform and report 65,409 results annually in Chemistry, Urinalysis, Endocrinology, Hematology, and Coagulation.