

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1084596	(X3) Date Survey Completed 01/27/2026
Name of Provider or Supplier Bhi Diagnostics	Street Address, City, State 8920 Wilshire Blvd, St 310, Beverly Hills, 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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the American Proficiency Institute (API) proficiency testing (PT) records and interviews with the testing personnel (TP) and technical consultant (TC), it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Routine Chemistry for the Uric acid analyte. The findings include: 1. The surveyor reviewed the PT records wherein API reported an unsatisfactory score of 60% for the Uric Acid analyte during the second event of 2025 (Q2-2025). The result are as followed: Sample Result Expected CH-06 2.5 1.9 - 2.5 CH-07 *10.1 7.9 - 9.8 CH-08 5.2 4.1 - 5.2 CH-09 7.8 6.3 - 7.8 CH-10 *14.1 9.9 - 12.2 Legend: * = unsatisfactory score 2. The TP and TC affirmed by interviews on January 27, 2026 at approximately 2:25 p.m. that the laboratory obtained the unsatisfactory PT score mentioned in statement #1. 3. The accuracy and reliability of patient tests reported cannot be determined. 4. According to the laboratory's testing declaration form (Lab-144) submitted on the day of the survey, the laboratory performed approximately 100,000 patient test samples annually for Routine CHEmistry which included the Uric Acid analyte during the time the laboratory received the unsatisfactory PT score. .</p>
D2098	<p>ENDOCRINOLOGY CFR(s): 493.843(a)</p> <p>(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing</p>

event.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the American Proficiency Institute (API) proficiency testing (PT) records, and interviews with the testing personnel (TP) and technical consultant (TC), the laboratory failed to attain at least 80 percent of the acceptable score in Endocrinology for the 25-OH Vitamin D analyte for the second event of 2025 (Q2-2025). The findings include: 1. The surveyor reviewed the API PT comparative evaluation documentation and found that the laboratory obtained an unsatisfactory score of 40% for the 25-OH Vitamin D analyte in Q2-2025 event. The report is as followed: Sample Result Expected IAS-06 *61 32 - 59 IAS-07 *78 37 - 75 IAS-08 26 13 - 34 IAS-09 12 6 - 21 IAS-10 *84 45-80 Legend: * = unsatisfactory score 2. The TP and TC affirmed by interviews on January 27, 2026, at approximately 2:25 p.m. that the laboratory obtained the unsatisfactory PT scores for the 25-OH Vitamin D analyte during the Q2-2025 event as mentioned in statement #1. 3. According to the laboratory's testing declaration, the laboratory performed and reported approximately 2,000 patient test samples for the 25-OH Vitamin D analyte annually including the time the laboratory received unsatisfactory proficiency testing scores. Thus, the accuracy and reliability of patient test reported cannot be determined. .

D2121

HEMATOLOGY

CFR(s): 493.851(a)

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the American Proficiency Institute (API) proficiency testing (PT) records, and interviews with the testing personnel (TP) and technical consultant (TC), it was determined that the laboratory failed to attain at least 80 percent of the acceptable response resulting to an unsatisfactory performance for the Hematology second event in 2024 (Q2-2024) for the White Blood Cell (WBC) count analyte. The findings include: 1. The laboratory was enrolled in the API PT program and received an unsatisfactory score of 60% for the WBC count analyte in the Q2-2024 event. 2. The TP and TC affirmed by interviews on January 27, 2026, at approximately 2:35 p.m. that the laboratory obtained the PT unsatisfactory scores as mentioned in statement #1. 3. According to the laboratory testing declaration submitted on the day of the survey, the laboratory performed approximately 35,000 samples annually for Hematology that included the WBC count analyte. Thus, the reliability and quality of Hematology patient results reported could not be assured at the time when the laboratory obtained unsatisfactory scores. .

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's policy and procedure, proficiency testing (PT) records and interviews with the testing personnel and technical consultant on January 27, 2026, it was determined that the laboratory failed to perform and document a corrective action for analytes that achieved an unsatisfactory score of less than 100 percent. The findings include: 1. The laboratory was enrolled with the American Proficiency Institute (API) PT program for the Vitamin D and Hemoglobin A1c analyte and obtained unsatisfactory scores of 80% for the first event of 2025. 2. The laboratory failed to follow their policy to perform a corrective action for any analyte that received an unsatisfactory score as both the Vitamin D and Hemoglobin A1c 80% scores had no documentation. 3. During the interview with the TP and TC on January 27, 2026, at approximately 2:25 p.m., both stated that no corrective action was performed nor documented for the first Vitamin D and Hemoglobin A1c analytes when a 80% unsatisfactory score was received. 4. According to the testing declaration form (Lab-144) submitted at the time of the survey, the laboratory performed and reported approximately 2,000 Vitamin D tests and 1,250 Hemoglobin A1c tests annually, including the time when unsatisfactory PT scores were received and corrective action was missed to be documented. .

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's proficiency testing documentation and interviews with the testing personnel and technical consultant on January 27, 2026, this deficiency is herein cited for the laboratory director due to failure to ensure that proficiency testing samples were tested as required under Subpart H of this part. 1. The laboratory obtained an unsatisfactory score for Routine Chemistry in the Uric Acid analyte. See D2087. 2. The laboratory obtained an unsatisfactory score for 25-OH Vitamin D analyte in the Endocrinology subspecialty. See D2098. 3. The laboratory obtained an unsatisfactory score for Hematology specialty in the White Blood Cell count analyte. See D2121. .

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;

This STANDARD is not met as evidenced by:
Based on the surveyor's review of the laboratory's policy and procedure, proficiency testing records from the American Proficiency Institute for the first event of 2025 and interviews with the testing personnel and technical consultant on January 27, 2026, the laboratory director is herein cited for failing to ensure that the laboratory followed an approved corrective action plan when any proficiency testing result received are found to be unacceptable or unsatisfactory. See D5221.