

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1010183	(X3) Date Survey Completed 06/13/2025
Name of Provider or Supplier Uptimum Medical Group And Ipa Inc	Street Address, City, State 2220 W Manchester Blvd, Inglewood, 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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(b)(7) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing records, and interview with the laboratory technical consultant on June 13, 2025, at 11:40 a.m., the laboratory failed to maintain the test records. The findings include: 1. The laboratory successfully participated in the API proficiency testing program for its CBC test. However, the laboratory did not have a copy of the instrument test record for the 2nd and 3rd events in 2024 and 1st event in 2025. Therefore, it cannot be determined if the laboratory indeed tested the proficiency testing sample that it reported to the API. Hence, the accuracy and quality of the laboratory services cannot be assured. 2. The laboratory technical consultant on June 13, 2025, at 11:40 a.m., affirmed that the laboratory did not save the proficiency testing records for some events in 2024 and 2025. 3. The laboratory's testing declaration form, signed by the laboratory director on 6/12/2025, stated that the laboratory performed approximately 9,600 CBC tests, annually.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) 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>

This STANDARD is not met as evidenced by:
 Based on Surveyor review of laboratory's CBC test records and procedure manual, and interview with the laboratory technical consultant on June 13, 2025, at 12:10 p.m., the laboratory failed to have the CBC test procedure manual. The findings include: 1. The laboratory performed CBC test using an automated instrument from Sysmex. The instrument print out showed a poor-quality sample flagged with an "*" mark by the platelet result for the patient ID 22023 ran on 6/12/2025, out of 10 patients' sample reviewed. The laboratory did not have a procedure manual, and the testing person did not know what to do with the flagged sample. The results were reported without any corrective action taken. Therefore, the accuracy of the patients' test results rendered by the laboratory cannot be assured since it used a poor-quality sample and may have harmed patient. 2. The laboratory technical consultant on June 13, 2025, at 12:10 p. m., affirmed that the laboratory did not have a procedure manual, and the testing person was not aware of any required corrective action for flagged results. 3. The laboratory's testing declaration form, signed by the laboratory director on 6/12/2025, stated that the laboratory performed approximately 9,600 CBC tests, annually.

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 Surveyor review of laboratory's proficiency testing records, and interview with the laboratory technical consultant on June 13, 2025, at 11:40 a.m., the laboratory director failed to ensure that the proficiency testing samples are tested accordingly. The findings include: See D2015.

D6031

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(e)(13)

(e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

This STANDARD is not met as evidenced by:
 Based on Surveyor review of laboratory's CBC test records and procedure manual, and interview with the laboratory technical consultant on June 13, 2025, at 12:10 p.m., the laboratory director failed to ensure that an approved CBC test procedure manual is available in the laboratory for the testing personnel to use. The findings include: See D5401.