Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1061856	(X3) Date Survey Completed 10/29/2021
Name of Provider or Supplier Icm Medical Group Inc	**Street Address, City, State** 211 N Prairie Ave, 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
D2087	ROUTINE CHEMISTRY CFR(s): 493.841(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 Surveyor review of laboratory's proficiency testing (PT) results from American Proficiency Institute (API) and interview with the laboratory technical consultant on October 29, 2021 at 12:10 pm, the laboratory failed to attain a score of at least 80 percent of acceptable responses for Alkaline Phosphatase (ALP) at the 3rd event of 2021. The findings include: 1. The laboratory performed ALP testing using an automated AU400 instrument. To verify its test accuracy, the laboratory participated in API PT testing for the year of 2021. However, it received a score of 0% at the 3rd event for the ALP resulting in an unsatisfactory analyte performance for the event. Therefore, the failure in the PT event suggesting that the patients' ALP results reported during the PT event period might had not been accurate and thus causing patient harm. 2. The laboratory technical consultant on October 29, 2021 at 12:10 pm, affirmed that the laboratory had received a score of 0% at the 3rd event for the ALP. 3. The laboratory's testing declaration form, signed by the laboratory Director on 10/23/2021, stated that the laboratory performs 1,500 ALP tests, annually.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be

	maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) results from American Proficiency Institute (API), remedial action documentation and interview with the laboratory technical consultant on October 29, 2021 at 12:20 pm, the laboratory failed to take an appropriate remedial action after obtaining an unsatisfactory analyte performance for Alkaline Phosphatase (ALP) at the 3rd event of 2021. The findings include: 1. The laboratory performed ALP testing using an automated AU400 instrument. To verify its test accuracy, the laboratory participated in API PT testing for the year of 2021, and obtained an unsatisfactory analyte performance at the 3rd event for the ALP. Therefore, the failure in the PT event suggesting that the patients' ALP results reported during the PT event period might had not been accurate and thus causing patient harm. However, the laboratory did not investigate any effect on patient care during that PT period. 2. The laboratory technical consultant on October 29, 2021 at 12:20 pm, affirmed that the laboratory's remedial action plan was not sufficient. 3. The laboratory's testing declaration form, signed by the laboratory Director on 10/23/2021, stated that the laboratory performs 1,500 ALP tests, annually.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's quality control (QC) results, calibration and calibration verification records and interview with the laboratory technical consultant on October 29, 2021 at 12:30 pm, the laboratory failed to perform and document calibration verification after Alkaline Phosphatase (ALP) QC results showed an unusual trend. The findings include: 1. The laboratory's ALP QC results showed a trend on Levey-Jennings chart on the month of August 2021. Both levels of controls

	were running below the mean for more than 7 consecutive runs. However, the laboratory did not perform calibration verification although it had a written procedure to do so. Therefore, the patients' ALP results reported during that time might had not been accurate and thus causing patient harm. 2. The laboratory technical consultant on October 29, 2021 at 12:30 pm, affirmed that the laboratory did not do calibration verification after seeing a trend for ALP QC. 3. The laboratory's testing declaration form, signed by the laboratory Director on 10/23/2021, stated that the laboratory performs 1,500 ALP tests, annually.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy & procedure, quality control (QC) records, proficiency testing (PT) results from American Proficiency Institute (API), lack of remedial action documentation and interview with the laboratory technical consultant on October 29, 2021 at 12:20 pm, the laboratory director failed to ensure compliance with the applicable regulations. The findings include: See D2087, D2094, D5439, D6019 and D6023.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iv) Ensure that 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 Surveyor review of laboratory's policy & procedure, proficiency testing (PT) results from American Proficiency Institute (API), lack of remedial action records and interview with the laboratory technical consultant on October 29, 2021 at 12:20 pm, the laboratory director failed to ensure that an approved corrective action plan is followed when the proficiency testing results of Alkaline Phosphatase (ALP) are found to be unacceptable or unsatisfactory. Findings include: The laboratory did not follow an approved corrective action plan after receiving unacceptable Proficiency testing evaluations from API for ALP. See D2094.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(6) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) results from American Proficiency Institute (API) and interview with the laboratory technical consultant on October 29, 2021 at 12:10 pm, the laboratory failed to attain a score of at least 80 percent of acceptable responses for Alkaline Phosphatase (ALP) at the 3rd event of 2021 and received an unsatisfactory analyte performance evaluation for the testing event. The findings include: See D2087.