

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0659993	<b>(X3) Date Survey Completed</b> 04/28/2021
<b>Name of Provider or Supplier</b> In-Vitro Diagnostics, Inc Db a Serolab	<b>Street Address, City, State</b> 7100 Old McGregor Road Suite A, Waco, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Based on a routine recertification survey conducted on April 28, 2021, the laboratory was found to be out of compliance based on the following <b>CONDITION LEVEL DEFICIENCIES</b> : D6033 - 42 C.F.R. 493.1409 Condition: Laboratories performing moderate complexity testing; technical consultant; D6108 - 42 C.F.R. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor;
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>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 <b>STANDARD</b> is not met as evidenced by: Based on review of proficiency testing records and interview with facility personnel, the laboratory failed to include 2 of 3 testing personnel in performing proficiency testing for 6 of 6 events between 2019 and 2020. The findings included: 1. Based on review of the analytic records for 6 of 6 College of American Pathologist proficiency testing challenges for IgE, 6 of 6 events were performed by Testing Personnel 3 (as listed on the CMS-209 Laboratory Personnel Report). 2. In an interview at 11:17 hours on 4/28/2021 in the front room, the laboratory supervisor stated that Testing Person 3 had "set up" the last six College of American Pathologist proficiency testing challenges.</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p>

This STANDARD is not met as evidenced by:  
Based on review of laboratory policy, accuracy assessment records, and interview with facility personnel, the laboratory failed to assess the accuracy twice annually for the IgG allergen specific testing in 2019 and 2020. The findings included: 1. Based on review of the facility policy "Internal Proficiency Testing Plan IgG", the policy stated the following: "1. Internal proficiency testing will be set up three times per year. 2. Pull five patients' sera that have been previously tested and have been shown to have both positive and negative test results for various specific IgG's. Volume for these 5 sera must total 5 mls. 3. Pool sera together in the same container for testing. 4. Samples will be split into two separate tubes and labeled with test patient accession number and date. One sample will be sent to Hycor Biomedical for comparison testing." 2. Based on review of accuracy assessment records, the laboratory performed the accuracy assessments one time in 2019 on 12/04/2019 and one time in 2020 on 11/24/2020. 3. In an interview at 10:40 hours on 4/28/2021, the surveyor requested documentation of a second assessment in both 2019 and 2020 and the laboratory supervisor stated the laboratory did not have documentation of a second assessment for 2019 and 2020. Key: Mls - milliliters IgG - Immunoglobulin G

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT  
CFR(s): 493.1252(b)**

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
Based on surveyor observations, review of temperature records, and interview with facility personnel, the laboratory failed to ensure the temperature of a laboratory refrigerator was within limits for storage of reagents and specimens for 181 of 181 days temperatures were recorded that were reviewed between August 2020 and April 2021. The findings included: 1. Based on surveyor observations at 13:58 hours on 4/28/2021 in the laboratory, the refrigerator labeled "REF SAMS" was at 10 degrees Celsius. The following items were stored in the refrigerator: 1 bottle of Hytec Probe Cleaning Solution - Reference 288197 - Storage requirements 2 to 8 degrees Celsius. 3 bottles of Hytec IgE diluent - Reference 309046 - Storage requirements 2 to 8 degrees Celsius. 1 box of Specific IgE calibrator set - Reference 74119 - Storage requirements 2 to 8 degrees Celsius. 17 bottles of Hytec Substrate Diluent - Reference 308050 - Storage requirements 2 to 8 degrees Celsius. 2. Based on an interview at 13:58 hours on 4/28/2021, the following 13 specimens had been stored in the REF SAMS refrigerator prior to their analysis on 4/28/21: 211170001S, 211170003S, 21117004S, 21117005S, 21117006S, 21117007S, 21117008S, 21117009S, 211170010S, 211170011S, 211170012S, 211170013S, 21117014S. Based on review of the Hycor instructions for use, under SPECIMEN COLLECTION AND HANDLING, the instructions state: "Only serum has been validated for this procedure. Obtain patient sample by non-traumatic venipuncture using a red-topped or serum separator vacuum tube. Allow the samples to clot at room temperature for at least 20 to 30 minutes, until the clot just begins to retract. Spin the serum in a centrifuge. Following centrifugation

transfer the serum to a 12x75mm tube. Cap the specimens and refer to the stability summary below for storage limitations. Refrigerated (2 to 8 degrees C): 21 days Frozen (less than or equal to -20 degrees C) : 6 months Transport Temperature: Ambient or cold packs" 3. Based on review of the laboratory temperature records, the refrigerator REF SAMS had not achieved acceptable temperatures between 2 and 8 degrees Celsius for 181 of the last 181 recorded measurements. In April 2021, 20 of 20 temperatures measurements were outside of acceptable ranges. In March 2021, 23 of 23 temperatures measurements were outside of acceptable ranges. In February 14 of 14 temperatures measurements were outside of acceptable ranges. In January 2021, 20 of 20 temperatures measurements were outside of acceptable ranges. In December 2020, 21 of 21 temperatures measurements were outside of acceptable ranges. In November of 2020, 19 of 19 temperatures measurements were outside of acceptable ranges. In October of 2020, 22 of 22 temperatures measurements were outside of acceptable ranges. In September of 2020, 21 of 21 temperatures measurements were outside of acceptable ranges. In August of 2020, 21 of 21 temperatures measurements were outside of acceptable ranges. The last acceptable temperature was recorded as 4 degrees Celsius on July 31, 2020. 4. In an interview at 14:10 hours on 4/28/2021 in the front room, the laboratory supervisor stated confirmed there had been an event in July 2020 and the refrigerator had not been as cold since the event.

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**  
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:  
Based on review of the Hycor Hytec 288 operator's manual, laboratory maintenance records, and interview with facility personnel, the laboratory failed to perform and document daily maintenance for 7 of 7 weeks between 3/8/21 and 4/26/21. The findings included: 1. Based on review of the Hycor Hytec 288 operator's manual, on page 86 under Maintenance, the manual stated: "All maintenance procedures must be performed with the frequency described, other the proper operation of the HYTEC 288 is not guaranteed. The frequent is indicated by characters meaning daily (D), weekly (W), monthly (M), half yearly (1/2Y) or yearly (Y)." The chart included the following daily maintenance tasks: Empty the waste bottle Make a backup of the database files Rinse the substrate bottle with DI water and let dry 2. Based on review of the maintenance documentation, the "Report: Maintenance Log Report" did not contain documentation of daily maintenance tasks (empty the waste bottle, making a backup of the database files, or rinse the substrate bottle with DI water) between 3/8 /21 and 4/26/21. 3. Based on review of the file pathway Hycor (C:) BackupDB on instrument number 1, Database backups were performed on the following dates: 3/8 /21, 3/15/21, 3/23/21, 3/29/21, 4/5/21, 4/9/21, 4/13/21, 4/19/21, 4/24/21, 4/26/21. In an interview at 13:40 hours on 4/28/2021 in the laboratory, the laboratory supervisor stated the database backups were automatically performed whenever staff would log out and log back into the instrument software. The laboratory supervisor also stated that the files were automatically backed up to a separate server through a laboratory router. When the surveyor requested the laboratory, supervisor verify the instrument was backed up to the separate server on a daily maintenance, the laboratory supervisor stated that the laboratory would need additional information technology support to confirm the extra server back-up. 4. In an interview at 13:45 hours on 4/28/2021 in the

front room, when the surveyor requested documentation of performing daily maintenance tasks between 3/8/21 and 4/26/21 for Instrument number 1, the laboratory supervisor stated the laboratory performed many of the daily maintenance tasks but did not keep separate documentation of the performance of these tasks.

**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 reappropriates 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 review of the laboratory's policies and procedures, the CMS Form 209 Laboratory Personnel Report, review of the laboratory's personnel records, and interview with facility personnel, the Laboratory Director failed to delegate competency assessments to an individual who qualified as a Technical Consultant under 493.1409 for competency assessments of 3 of 3 testing personnel performing moderate complexity testing in 2019 and 2020. The findings included: 1. Based on a review of the laboratory's policy "Delegation of Authority", the document states: "Acting in my capacity of Laboratory Director, Clinical Consultant, and Technical Supervisor for Serolab, I hereby delegated the following responsibilities to my Supervisor: 5. Annually evaluating and documenting the performance competency of all testing personnel." This document was signed by the Laboratory Director on 1/13 /2017. 2. Based on review of the laboratory's procedure "Laboratory Staff Orientation, Training and Assessment", approved for use by the laboratory director on 3/28/2013, the procedure states: "ANNUAL EVALUATION AND COMPETENCY OF STAFF Each employee will be evaluated for competency at six months from hire and annually thereafter. The Laboratory Director, General Supervisor, or Technical Consultant will visually examine and review each employee's understanding and performance in each area of responsibility. This review will include the pre-analytical (order, collection and handling of specimen, requisition and processing), analytical (actual performance of the test, including maintenance and quality control) and postanalytical (review of results, documentation and release of results to patient record) phases of testing. Additional competency may be evaluated by review of proficiency testing records: by showing acceptable performance, documentation, review, and corrective action. The Laboratory Director, General Supervisor, or Technical Consultant may assess further evaluation and competency through the facility administrator or other persons on site in authority. If an employee fails to demonstrate satisfactory performance on the competency assessment, the General Supervisor shall initiate a plan of corrective action to re-train and re-assess the employee's competency. Documentation of re-training and reassessment must be maintained by the General Supervisor and another copy placed in the employees personnel file." 3. Based on review of the personnel records and the CMS Form 209 Laboratory Personnel Report, the laboratory director was the only individual listed as a Technical Consultant. 4. In an interview at 09:49 on 4/28/2021 in the laboratory,

Testing Person 1 stated that she had performed the direct observation routine testing and maintenance of Testing Persons 2 and 3 as part of the competency assessments in 2019 and 2020. Based on review of the laboratory personnel records for 2019 and 2020, the competency assessments had been performed by Testing Person 1 as listed on the CMS Form 209 Laboratory Personnel Report and later signed by the laboratory director. Testing Person 1 does not qualify as a Technical Consultant under 493.1409.

**D6033**

**TECHNICAL CONSULTANT-MODERATE COMPEXITY**  
CFR(s): 493.1409

The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of laboratory policies and procedures, testing personnel competency assessments, and interview with facility personnel, the Technical Consultant failed to provide technical oversight of the laboratory for 2 of 2 years in 2019 and 2020. The findings included: 1. Based on review laboratory policies, personnel competency assessments, and interview with facility personnel, the Technical Consultant failed to perform competency assessments of 3 of 3 testing personnel in 2019 and 2020 for moderate complexity allergen testing. Refer to D6046.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, the CMS Form 209 Laboratory Personnel Report, review of the laboratory's personnel records, and interview with facility personnel, the technical consultant failed to perform annual competency assessments of 3 of 3 testing personnel in 2019 and 2020. The findings included: 1. Based on a review of the laboratory's policy "Delegation of Authority", the document states: "Acting in my capacity of Laboratory Director, Clinical Consultant, and Technical Supervisor for Serolab, I hereby deleted the following responsibilities to my Supervisor: 5. Annually evaluating and documenting the performance competency of all testing personnel." This document was signed by the Laboratory Director on 1/13/2017. 2. Based on review of the laboratory's procedure "Laboratory Staff Orientation, Training and Assessment", approved for use by the laboratory director on 3/28/2013, the procedure states: "ANNUAL EVALUATION AND COMPETENCY OF STAFF Each employee will be evaluated for competency at six months from hire and annually thereafter. The Laboratory Director, General Supervisor, or Technical Consultant will visually examine and review each employee's understanding and performance in each area of responsibility. This review will include the pre-analytical (order, collection and handling of specimen, requisition and processing), analytical (actual performance of the test, including maintenance and quality control) and postanalytical (review of results, documentation and release of results to patient record) phases of testing. Additional competency may be evaluated

by review of proficiency testing records: by showing acceptable performance, documentation, review, and corrective action. The Laboratory Director, General Supervisor, or Technical Consultant may assess further evaluation and competency through the facility administrator or other persons on site in authority. If an employee fails to demonstrate satisfactory performance on the competency assessment, the General Supervisor shall initiate a plan of corrective action to re-train and re-assess the employee's competency. Documentation of re-training and reassessment must be maintained by the General Supervisor and another copy placed in the employees personnel file." 3. Based on review of the personnel records and the CMS Form 209 Laboratory Personnel Report, the laboratory director was the only individual listed as a Technical Consultant. 4. In an interview at 09:49 on 4/28/2021 in the laboratory, Testing Person 1 stated that she had performed the direct observation routine testing and maintenance of Testing Persons 2 and 3 as part of the competency assessments in 2019 and 2020. Based on review of the laboratory personnel records for 2019 and 2020, the competency assessments had been performed by Testing Person 1 as listed on the CMS Form 209 Laboratory Personnel Report and later signed by the laboratory director.

**D6079**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reappoints 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 review of the laboratory's policies and procedures, the CMS Form 209 Laboratory Personnel Report, review of the laboratory's personnel records, and interview with facility personnel, the Laboratory Director failed to delegate competency assessments to an individual who qualified as a Technical Supervisor or General Supervisor under 493.1447 or 493.1459 to perform competency assessments of 1 of 1 testing personnel performing high complexity testing in 2019 and 2020. The findings included: 1. Based on a review of the laboratory's policy "Delegation of Authority", the document states: "Acting in my capacity of Laboratory Director, Clinical Consultant, and Technical Supervisor for Serolab, I hereby delegated the following responsibilities to my Supervisor: 5. Annually evaluating and documenting the performance competency of all testing personnel." This document was signed by the Laboratory Director on 1/13/2017. 2. Based on review of the laboratory's procedure "Laboratory Staff Orientation, Training and Assessment", approved for use by the laboratory director on 3/28/2013, the procedure states: "ANNUAL EVALUATION AND COMPETENCY OF STAFF Each employee will be evaluated for competency at six months from hire and annually thereafter. The Laboratory Director, General Supervisor, or Technical Consultant will visually examine and review each employee's understanding and performance in each area of responsibility. This review will include the pre-analytical (order, collection and handling of

specimen, requisition and processing), analytical (actual performance of the test, including maintenance and quality control) and postanalytical (review of results, documentation and release of results to patient record) phases of testing. Additional competency may be evaluated by review of proficiency testing records: by showing acceptable performance, documentation, review, and corrective action. The Laboratory Director, General Supervisor, or Technical Consultant may assess further evaluation and competency through the facility administrator or other persons on site in authority. If an employee fails to demonstrate satisfactory performance on the competency assessment, the General Supervisor shall initiate a plan of corrective action to re-train and re-assess the employee's competency. Documentation of re-training and reassessment must be maintained by the General Supervisor and another copy placed in the employees personnel file." 3. Based on review of the personnel records and the CMS Form 209 Laboratory Personnel Report, the laboratory director was the only individual listed as a Technical Supervisor or General Supervisor. 4. In an interview at 09:49 on 4/28/2021 in the laboratory, Testing Person 1 stated that she had performed the direct observation routine testing and maintenance of Testing Persons 2 and 3 as part of the competency assessments in 2019 and 2020. Based on review of the laboratory personnel records for 2019 and 2020, the competency assessments had been performed by Testing Person 1 as listed on the CMS Form 209 Laboratory Personnel Report and later signed by the laboratory director. Testing Person 1 does not qualify as a Technical Supervisor or General Supervisor under 493.1447 or 493.1459.

**D6108**

**LABORATORY TECHNICAL SUPERVISOR**  
CFR(s): 493.1447

The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

This CONDITION is not met as evidenced by:  
Based on review of laboratory policies and procedures, testing personnel competency assessments, and interview with facility personnel, the Technical Supervisor failed to provide technical oversight of the laboratory for 2 of 2 years in 2019 and 2020. The findings included: 1. Based on review laboratory policies, personnel competency assessments, and interview with facility personnel, the Technical Supervisor failed to perform competency assessments of 1 of 1 testing personnel in 2019 and 2020 for high complexity allergen testing. Refer to D6120.

**D6120**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**  
CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:  
Based on review of the laboratory's policies and procedures, the CMS Form 209

Laboratory Personnel Report, review of the laboratory's personnel records, and interview with facility personnel, the Technical Supervisor failed to perform annual competency assessments of 1 of 1 high complexity testing personnel in 2019 and 2020. The findings included: 1. Based on a review of the laboratory's policy "Delegation of Authority", the document states: "Acting in my capacity of Laboratory Director, Clinical Consultant, and Technical Supervisor for Serolab, I hereby delegate the following responsibilities to my Supervisor: 5. Annually evaluating and documenting the performance competency of all testing personnel." This document was signed by the Laboratory Director on 1/13/2017. 2. Based on review of the laboratory's procedure "Laboratory Staff Orientation, Training and Assessment", approved for use by the laboratory director on 3/28/2013, the procedure states: "ANNUAL EVALUATION AND COMPETENCY OF STAFF Each employee will be evaluated for competency at six months from hire and annually thereafter. The Laboratory Director, General Supervisor, or Technical Consultant will visually examine and review each employee's understanding and performance in each area of responsibility. This review will include the pre-analytical (order, collection and handling of specimen, requisition and processing), analytical (actual performance of the test, including maintenance and quality control) and postanalytical (review of results, documentation and release of results to patient record) phases of testing. Additional competency may be evaluated by review of proficiency testing records: by showing acceptable performance, documentation, review, and corrective action. The Laboratory Director, General Supervisor, or Technical Consultant may assess further evaluation and competency through the facility administrator or other persons on site in authority. If an employee fails to demonstrate satisfactory performance on the competency assessment, the General Supervisor shall initiate a plan of corrective action to re-train and re-assess the employee's competency. Documentation of re-training and reassessment must be maintained by the General Supervisor and another copy placed in the employees personnel file." 3. Based on review of the personnel records and the CMS Form 209 Laboratory Personnel Report, the laboratory director was the only individual listed as a Technical Supervisor. 4. In an interview at 09:49 on 4/28/2021 in the laboratory, Testing Person 1 stated that she had performed the direct observation routine testing and maintenance of Testing Persons 2 and 3 as part of the competency assessments in 2019 and 2020. Based on review of the laboratory personnel records for 2019 and 2020, the competency assessments had been performed by Testing Person 1 as listed on the CMS Form 209 Laboratory Personnel Report and later signed by the laboratory director.