

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0659993	<b>(X3) Date Survey Completed</b>  01/09/2019
<b>Name of Provider or Supplier</b>  In-Vitro Diagnostics, Inc DbA 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>D5469</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality control instructions for use, laboratory policies and procedures, quality control records, and interview with facility personnel, the laboratory failed to accurately establish acceptability for two of two lots of controls reviewed between 2017 and 2018. The findings included: 1. Based on review of the Hycor Specific and Total IgE Controls (Ref 71207), the instructions for use states the following under EXPECTED VALUES: "The control ranges listed have been established by Hycor Biomedical. Because of differences in reagent lots and individual laboratory equipment, it is recommended that these values be used as guidelines to aid in establishing a range with accurately reflects user performance." 2. Based on review of the laboratory's procedure titled "Technical Procedure for Total IgE Testing EIA", approved by the laboratory director on 1/9/17, under QUALITY CONTROL, states the following: "Mean values with acceptable ranges are established internally and are used to monitor assay performance. The Levy-Jennings graphs,</p>

available within each of the 4 Hytec 288 analyzers, will be printed on a monthly basis and reviewed for shifts and trends, accuracy, and precision. Ranges for each new lot of liquid controls are generally determined by calculating the mean and standard deviation from 20 replicate runs performed over at least 3 days if possible. The target is set at plus or minus two standard deviations from the mean unless specifically stated otherwise within the assays procedure. The new lab mean must fall within the manufacturer's stated range to be valid." 3. Based on review of the quality control records, the ranges established for Lot 154102 included a value of 172.24, which is outside the guidelines for lot 154102 (339 - 903) and the laboratory calculated a plus or minus 1 standard deviation acceptable range. This lot was in use on 6/23/2017. The range established by the laboratory was 462.5 - 670. Based on review of quality control bar graphs for instrument 1, the laboratory obtained a value of 451.05 on 7/13/2017, below the 462.5 - 670 established by the lab. There are no repeats for quality control on 7/13/2017 for Instrument 1. Based on review of quality control bar graphs for instrument 4, the laboratory obtained a value of 690.64 on 7/14/2017, above the 462.5 - 670 established by the lab. There are no repeats for quality control on 7/14/2017 for Instrument 4. 4. Based on review of the quality control records, the ranges established for Lot 156484 included a value of 11.06, which is outside the guidelines for lot 156484 (265-806) and the laboratory calculated a plus or minus 1 standard deviation acceptable range. This lot was in use on 12/03/2018. The range established by the laboratory was 462.35 - 748.89. Based on review of quality control bar graphs for instrument 4, the laboratory obtained a value of 779.89 on 12/11/2018, above the 462.35 - 748.89 established by the lab. There are no repeats for quality control on 12/11/2018 for Instrument 4. Based on review of quality control bar graphs for instrument 4, the laboratory obtained a value of 350.97 on 12/13/2018, below the 462.35 - 748.89 established by the lab. There are no repeats for quality control on 12/13/2018 for Instrument 4. Based on review of quality control records, the laboratory was not printing Levy-Jennings graphs as required by established laboratory policy. The laboratory was printing bar graphs. Additionally, the laboratory was not entering the established limits into the quality control program. Using the bar graph methodology, the laboratory is not able to accurately distinguish values between the mean, and plus or minus 1, 2, or 3 standard deviations away from the mean. 4. In an interview at 14:00 hours on 1/8/2015 in the laboratory, the Laboratory Manager stated the laboratory had been unaware the outlying values were included in the acceptability range establishment or that the laboratory had established a plus or minus one standard deviation acceptability range instead of a plus or minus two standard deviation range as required by the laboratory policy.

**D6042**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(4)

(b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results;

This STANDARD is not met as evidenced by:  
Based on review of quality control instructions for use, laboratory policies and procedures, quality control records, and interview with facility personnel, the Technical Consultant failed to ensure the laboratory established the parameters for acceptable levels of analytic performance and ensuring that these levels are

maintained throughout the entire testing process for two of two lots of controls reviewed between 2017 and 2018. The findings included: 1. Based on review of the Hycor Specific and Total IgE Controls (Ref 71207), the instructions for use states the following under EXPECTED VALUES: "The control ranges listed have been established by Hycor Biomedical. Because of differences in reagent lots and individual laboratory equipment, it is recommended that these values be used as guidelines to aid in establishing a range with accurately reflects user performance." 2. Based on review of the laboratory's procedure titled "Technical Procedure for Total IgE Testing EIA", approved by the laboratory director on 1/9/17, under QUALITY CONTROL, states the following: "Mean values with acceptable ranges are established internally and are used to monitor assay performance. The Levy-Jennings graphs, available within each of the 4 Hytec 288 analyzers, will be printed on a monthly basis and reviewed for shifts and trends, accuracy, and precision. Ranges for each new lot of liquid controls are generally determined by calculating the mean and standard deviation from 20 replicate runs performed over at least 3 days if possible. The target is set at plus or minus two standard deviations from the mean unless specifically stated otherwise within the assays procedure. The new lab mean must fall within the manufacturer's stated range to be valid." 3. The Technical Consultant failed to ensure that the laboratory established a plus or minus two standard deviation acceptability criteria as required by the laboratory's procedure. 4. The Technical Consultant failed to ensure that the laboratory did not include extreme outliers in the establishment of acceptability ranges for two of two lots of control materials. 5. The Technical Consultant failed to ensure the laboratory printed Levy-Jennings graphs monthly to be review for shifts and trends, accuracy, and precision, as required by the laboratory's procedure. The laboratory had printed bar graphs that do not include accuracy or precision statistics such as mean, standard deviation, or coefficient of variation. The bar graphs do not display the relationship between the daily values and accuracy or precision statistics such as mean, standard deviation, or coefficient of variation. Refer to D5469.