

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2298573	(X3) Date Survey Completed 04/03/2025
Name of Provider or Supplier Atvivo Llc/DbA Atvivo Diagnostics	Street Address, City, State 110b Meadowlands Pkwy, Secaucus, NJ	
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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observation of Quality Control (QC) material in use, review of the Control Kits Manufacturers Package Insert (MPI) and interview with the Laboratory Director (LD), the laboratory failed to put correct expiration dates on QC material for the routine chemistry, Immunology and Endocrinology tests from 2/1/24 to 4/3/25. The findings include: 1. The expiration date of the QC material shortens once opened. 2. The laboratory had an open date of 3/17/25 and expiration date of 4/17/25 (30 days of stability) on Liquichek Specialty Immunology QC material in use. a) The MPI states Parathyroid hormone (PTH) had 7 days stability. 3. The laboratory had an open date of 3/28/25 and expiration date of 4/28/25 (30 days of stability) on Liquichek Immunology Control QC material in use. a) The MPI states Rheumatoid Factor had 10 days stability. 4. The laboratory had an open date of 4/1/25 and expiration date of 5/1/25 (30 days of stability) on Liquichek Immunoassay Plus Control QC material in use. a) The MPI states all analytes have a 14 day stability except Estradiol: 5 days and Folate: 4 days. 5. The laboratory had an open date of 4/2/25 and expiration date of 5/1/25 (30 days of stability) on Liquid Assayed Multiquel QC material in use. a) The MPI states all analytes have a 14 day stability except Alkaline Phosphatase, (AST /SGOT) Bilirubin (total): 9 days b) Bilirubin (Direct), Cholesterol (HDL), Creatine Kinase (CK), Phosphorus and Triglycerides: 7 Days 6. The LD confirmed on 4/2/25 at 11:45 am, the laboratory failed to put correct expiration dates on the QC material.</p>

D5421

ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

CFR(s): 493.1253(b)(1)

(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on surveyor review of Performance Specification (PS) records and interview with the Laboratory Director (LD), the laboratory failed to ensure that all PS records were adequate for all analytes run on the Atellica CH930, Atellica CH1600 and Advia 2120i Analyzers from February 2024 to 4/3/25. The findings include: 1. There was no Normal Patient Range study performed. 2. The LD confirmed on 4/3/25 at 11:30 am, the laboratory failed to ensure that all PS records were adequate.

D5469

CONTROL PROCEDURES

CFR(s): 493.1256(d)(10)(g)

(d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(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. (d)(10)(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. (d)(10)(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.

This STANDARD is not met as evidenced by:

Based on the lack of Quality Control Verification (QCV) records and interview with the Laboratory Director (LD), the laboratory failed to verify commercially assayed QC material with each new lot and/or shipment used on the Atellica CH930 and Atellica CH1600 from February 2024 to 4/3/25. The finding includes: 1. There were no QCV records available for review for the above mentioned analyzers. 2. The LD confirmed on 4/2/25 at 12:20 pm, the assayed values of QC material were not verified before being put into use.