Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1088854	06/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
The Hospital At Westlake 360	5656 Bee Cave Road Bldg L 2nd Floor, Austin, TX	

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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on surveyor observations and interview with facility personnel, the laboratory failed to label 2 of 2 large containers in the frozen section work room with storage requirements, preparation dates, and expiration dates on June 19th, 2018. The findings included: 1. At 11:21 hours on 6/19/218, the surveyor observed two (2) large, clear containers on top of the cryostat in the frozen section work room: a) Container 1 was labeled with a sticker that stated "10% Formalin: CAUTION CONTAINS FORMALDEHYDE, Toxic by inhalation and if swallowed irritating to the eyes, respiratory systems, and skin. May cause sensitization by inhalation or skin contact. Risk of serious damage to eyes. Potential cancer hazard. Repeated or prolonged exposure increased the risk." Container 1 was not labeled with the preparation date of the aliquot, the expiration date of the contents, or the storage requirements. b) Container 2 was labeled with a sticker that stated "10% Formalin: CAUTION CONTAINS FORMALDEHYDE, Toxic by inhalation and if swallowed irritating to the eyes, respiratory systems, and skin. May cause sensitization by inhalation or skin contact. Risk of serious damage to eyes. Potential cancer hazard. Repeated or prolonged exposure increased the risk." There was a biohazard sticker on the top of the container and the words "fornylacelyl-alcohol" written on the lid and the body of the container. The container had the date 4/12/2017 on the side, but it was not clear if it was a preparation date or expiration date. No storage requirements or concentration were found on the container. 2. In an interview at 11:23 hours on 6/19/2018, the

	Laboratory Manager confirmed the two (2 of 2) aliquots were missing required information.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (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 a review of the Vitros 350 verification studies, laboratory policy, assay instructions for use, patient records, and interview with facility personnel, the laboratory failed to verify 14 of 19 manufacturer reference ranges were appropriate for the laboratory's patient population. The findings included: 1. Based on review of the Vitros 350 chemistry analyzer (Serial number 27005075) verification study performed in March and April of 2017, the laboratory performed a reference range verification on the following 19 assays: Glucose Blood Urea Nitrogen (BUN) Creatinine Sodium (Na) Potassium (K) Chloride (Cl) Carbon Dioxide (CO2) Calcium (Ca) Total Protein (TP) Albumin (ALB) Aspartate Aminotransferase (AST) Alanine Transaminase (ALT) Alkaline Phosphatase (ALP) Total Bilirubin Amylase Lipase Magnesium Phosphorus Creatinine Kinase (CK) 2. Based on review of the laboratory policy "Reference Range Verification", adopted May 10, 2005, under section III: Reference Range Verification Frequency, the procedures state the following: "Verification of the reference range is requirement prior to reporting of patient results. An initial random sampling using representative samples will usually provide sufficient data to verify the manufacturer's reference range." Under the section V. Procedure: "1. When initiating a new procedure, unless the population to which it will be applied is known to be atypical or unusual, the manufacturer's established range is used as the referend range until the Reference Range Verification procedure is completed. A record must be kept of all patient results reported out prior to completion of the verification procedure." 3. Based on review of the Vitros 350 instructions for use, the manufacturer reference ranges differed from the laboratory's reference ranges as follows: Assay: Albumin Vitros manufacturer reference range: 3.5- 5.0 g/dL Reference range verified by the laboratory: 2.9 - 5.0 g/dL Assay: Alanine Transaminase (ALT) Vitros manufacturer reference range -Males: 21 - 72 U/L Vitros manufacturer reference range - Females: 9 - 52 U/L Vitros manufacturer reference range - Adults: 13 - 69 U/L Reference range verified by the laboratory: 11 -66 U/L Assay: Blood Urea Nitrogen (BUN) Vitros manufacturer reference range - Males: 9 - 20 mg/dL Vitros manufacturer reference range - Females: 7 -17 mg/dL Reference range verified by the laboratory: 8 -25 mg/dL Assay: Calcium Vitros manufacturer reference range: 8.4 -10.2 mg/dL Reference range verified by the laboratory: 8.5 - 10.5 mg/dL Assay: Carbon Dioxide (CO2) Vitros manufacturer reference range: 22 - 30 mmol/L Reference range verified by the laboratory: 18 - 30 mmol/L Assay: Creatinine Kinase (CK) Vitros manufacturer reference range -Males: 55 -170 U/L Vitros manufacturer reference range - Females: 30 - 135 U/L Reference range verified by the laboratory: 37 - 289 U/L Assay: Creatinine (Crea) Vitros manufacturer reference range -Males: 0.66 - 1.25 mg/dL Vitros manufacturer

	reference range - Females: 0.52 -1.04 mg/dL Reference range verified by the laboratory: 0.6 - 1.3 mg/dL Assay: Magnesium Vitros manufacturer reference range: 1.6 - 2.3 mg/dL Reference range verified by the laboratory: 1.3 - 2.3 mg/dL Assay: Sodium (Na) Vitros manufacturer reference range: 137 - 145 mmol/L Reference range verified by the laboratory: 133 -146 mmol/L Assay: Glucose Vitros manufacturer reference range: 74- 106 mg/dL Reference range verified by the laboratory: 65 - 100 mg/dL Assay: Potassium Vitros manufacturer reference range: 3.5 -5.1 (serum) mmol /L Plasma may be 0.1 - 0.7 mmol/L lower than serum range Reference range verified by the laboratory: 3.5 - 5.3 mmol/L Assay: Chloride Vitros manufacturer reference range: 98 -107 mmol/L Reference range verified by the laboratory: 97 - 110 mmol/L Assay: Total Protein Vitros manufacturer reference range: 6.3 - 8.2 g/dL Reference range verified by the laboratory: 6.0 - 8.4 g/dL Assay: Total Bilirubin Vitros manufacturer reference range: 0.2 - 1.3 mg/dL Reference range verified by the laboratory: 0.1 -1.3 mg/dL 4. Based on a random review of patient final reports, the reference ranges of unknown origin that were verified by the laboratory were used on the final patient reports. Examples: Patient: 0144027 Verified on 6/19/2018 Glucose value: 105 Reference range on final patient report: 65 -100 mg/dL Vitros 350 manufacturer reference range: 74 - 106 Patient: 0144035 - Female Verified on 6/18 /2018 Creatinine value: 0.8 mg/dL Reference range on final patient report: 0.6 - 1.3 mg /dL Vitros manufacturer reference range - Females: 0.52 -1.04 mg/dL 5. In an interview at 12:21 hours on 6/20/2018 in the office, the Laboratory Manager stated the origin of the discrepant reference ranges was not known and had been in place prior to her date of hire. Key: g/dL -grams per deciliter U/L - units per liter mmol/L - millimols/Liter
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's Individualized Quality Control Plan (IQCP) procedure and interview with facility personnel, the laboratory failed to identify the frequency and potential impact for each potential source of error identified in the laboratory's Risk Assessment (RA) for the Alere hCG Combo Cassette. The findings included: 1. Based on review of Food and Drug Administration (FDA) decision summary K993065, the analyte hCG is moderate complexity on the Alere hCG Combo Cassette when the specimen source is serum. 2. Review of the Risk Assessment portion of the IQCP for the Alere hCG Combo Cassette, signed by the laboratory director on 12/01/2016, included potential sources of error and mitigation strategies. The Risk Assessment DID NOT include the frequency with which the laboratory defined potential sources of error had occurred or were likely to occur. As a potential risk, the laboratory identified "Are specimens properly collected and are rejected specimens correctly documented? The laboratory failed to identify the frequency of improperly collected specimens for the Alere hCG Combo Cassette

	serum testing. 3. The Risk Assessment DID NOT include an assessment of the potential impact on patient results for each laboratory defined potential source of error. The lab defined "Do all testing personnel have documented training in all aspects of the test method?" as a potential risk of error. The laboratory did not define the potential impact on patient testing when testing personnel have not been trained in all aspects of the test method. 4. In an interview at 14:13 hours on 06/20/2018 in the office, the Laboratory Manager stated that the laboratory monitored potential sources of error through quality assurance activities but had not defined the frequency and impact of each source of error as part of the IQCP risk assessment. Key: hCG -Human chorionic gonadotropin
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(g) 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--Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of AimTab Ketone Tablet instructions for use, laboratory quality control records, patient records, and interview with facility personnel, the laboratory failed to use a control material of a similar matrix to serum 4 of 4 days patients were tested between January 25, 2018 and June 11, 2018. The findings included: 1. Based on review of the AimTab Ketone Tablet instructions for use (Lot: 71093, Expiration: 1 /31/2019), under QUALITY CONTROL: "Performance can be confirmed by suing commercially available positive and negative control materials. Contact Germaine Laboratories at 210-692-4192 for a list of acceptable control materials." 2. Based on a review of quality control and patient testing records from January 25, 2018 and June 11, 2018, serum ketone testing was performed on four (4) patient samples on four (4) days: Date: 1/25/2018 Patient: 0140158 Results: Negative Date: 03/21/2018 Patient: 0141691 Results: Small Date: 03/25/2018 Patient: 0141757 Results: Negative Date: 06 /11/2018 Patient: 0143729 Results: Negative Quality control was documented as being acceptable on all four (4) dates: 1/25/2018, 3/21/2018, 3/25/2018, and 6/11 /2018. 3. In an interview at 13:45 hours on 6/19/2018, when asked what control materials were used on the dates listed above, the Laboratory Manager stated the lab used Kova-Trol Human Urinalysis Controls. When asked if the laboratory had a control material with a similar matrix to serum, the Lab Manager stated the lab did not have a serum quality control material and had always used urine matrix controls to assess the performance of serum AimTab ketone tab performance.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality managment policy, quality assessment

	records, quality control records, laboratory policies and procedures, patient records, and interview with facility personnel, the laboratory failed to establish and follow quality assessment policies and procedures to identify, monitor, assess, and correct problems in analytic sytems between April 2017 and June 20, 2018. The findings included: 1. The laboratory's quality assessment procedures failed to detect that the laboratory failed to label 2 of 2 large containers in the frozen section work room with storage requirements, preparation dates, and expiration dates on June 19th, 2018. Refer to D5415. 2 The laboratory's quality assessment procedures failed to detect that the laboratory failed to verify 14 of 19 manufacturer reference ranges were appropriate for the laboratory's patient population. Refer to D5421. 3 The laboratory's quality assessment procedures failed to detect that the laboratory failed to identify the frequency and potential impact for each potential source of error identified in the laboratory's Risk Assessment (RA) for the Alere hCG Combo Cassette. Refer to D5445. 4. The laboratory's quality assessment procedures failed to detect that the laboratory failed to use a control material of a similar matrix to serum 4 of 4 days patients were tested between January 25, 2018 and June 11, 2018. Refer to D5465.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assessment records, Vitros 350 chemistry analyzer assay instructions for use, analyzer verification records, quality control records, patient test records, and staff interview, the laboratory director failed to ensure that the quality assessment program was maintained to assure the quality of laboratory services. The findings included: 1. The laboratory director failed to ensure policies and procedures were established and followed to detect problems in analytic laboratory systems. Refer to D5791.