Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0285781	04/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Hca Florida Westside Hospital	8201 W Broward Blvd, Plantation, FL	

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
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on record review, observation, and interview with Technical Supervisor B the laboratory failed to follow manufacturer's instruction for labeling quality control and test strips for the glucometers located in the Emergency Department. Findings Included: Review of the manufacturer's instructions (MI) for the Nova StatStrip blood glucose monitoring system state that "Controls are valid for 90 days after opened, not to exceed the manufacturer's expiration date. Record the new expiration date on each vial." It also stated that "Glucose test strips are valid for 180 days after opened, not to exceed the manufacturer's expiration date. Record the open date and new expiration date on the test vial." Tour of the Emergency Department on 04/15/2021 at 11:45 AM revealed 2 bottles of test strips (Lot#0320265249, Expiration 09/21/2022). One bottle did not have an open or discard date and the second bottle did not have a discard date. There were 2 bottles of low level control (Lot#0420095301 Expiration 10/04/2022) both had a discard date of 03/06/2022 and a high level control (Lot#0420016303 Expiration 07/16/2022) that had a discard date of 03/06/2022. Both of these dates would exceed the MI of only being valid for 90 days after opening. Interview on 04/15 /2021 at 11:45 AM Technical Supervisor B confirmed that the controls and strips were not labeled per the MI.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish

	and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to follow their Training and Competency policy for the 2020 annual competency assessments for 4 (A, B, C, E) of 6 (A, B, C, D, E, F) Testing Personnel reviewed. Findings included: Review of the Training and Competency Procedure, section VI Competency Assessment, F, #2 notes "Monitoring records of reported information (paper or electronic) which must include the following: Name of test or task and date of records." Review of the competency assessment showed for the moderate complexity testing performed in patient care areas of the hospital, 4 (A, B, C, E) Testing Personnel's competency assessments failed to indicate which tests the Testing Personnel were being evaluated on. During an interview on 04/15/2021 at 4:35 PM, the Technical Supervisor B stated the annual competency evaluations did not indicate which tests the Testing Personnel were being evaluated on.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on staff interview and record review of the Quality Assurance (QA) and Improvement Plan (IP); the laboratory failed to identify the correct specimen processing times and storage temperatures for the Abbott ID NOW COVID-19 implemented in September 2020. Findings included: a) Review of the QA and IP approved in December of 2020, shows the Indicators for the Performance/Quality Plan components. In Section VI of the plan, it lists the Pre-Analytical Process indicators to monitor patient preparation, specimen collection, labeling, preservation, transport of specimens and rejection of specimens. Also, in Section VI, the Analytical Process indicators require the review of new technologies, and this was not performed for the Abbott ID NOW COVID-19 test. b) Review of the IP appraisal for 2020, revealed that: - The laboratory failed to correct and assess the deficiencies associated with specimen collection, storage and processing time for the Abbott ID NOW COVID-19 implemented on September 2020. Refer to D5305 and D5411. -The laboratory failed to review the Abbott ID NOW COVID-19 test implemented in September 2020 and to correct the deficiencies associated with the test processing time. c) Review of the goals for IP 2021, revealed that the laboratory failed to include the review of the turn around time for the Abbott ID NOW COVID-19 test results. Refer to D5305 and D5411. During an interview on 4/16/21 at 4:00 PM, the laboratory director acknowledged that the QA failed to correct the deficiencies listed above.
D5305	TEST REQUEST CFR(s): 493.1241(c)

	The laboratory must ensure the test requisition solicits the following information: (1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to ensure the test requisition included the specimen collection time for the COVID-19 specimens it receives for the Abbott ID NOW COVID-19 test. Findings Included: Review of patients records revealed the following specimens received by the laboratory without a collection time were tested on the Abbott ID NOW instrument. 1. COVID-19 Patient 1 specimen was collected at unknown and received at 10:53 AM on 03/01 /2021 . 2. COVID-19 Patient 2 specimen was collected at unknown and received at 11: 55 AM on 03/01/2021 . 3. COVID-19 Patient 3 specimen was collected on unknown and tested at 2:13 PM on 03/02/2021 . 4. COVID-19 Patient 4 specimen was collected on unknown and tested at 7:06 PM on 03/01/2021 5. COVID-19 Patient 5 specimen was collected on unknown and tested at 11 09 on 3/01/2021. 6. COVID-19 Patient 6 specimen was collected on unknown and tested at 12:00 PM on 3/09/2021. 7. COVID-19 Patient 7 specimen was collected on unknown and tested at 11:19 am on 3/11 /2021. During an interview on 4/16/21 at 10:45, Technical Supervisor C acknowledged patient samples had no collection times.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to follow Abbott ID NOW COVID-19 manufacturer's specimen acceptability and rejection guidelines for COVID-19 specimens from September 23, 2020 to present. Findings Included: Review of the Abbott technical brief - September 2020 stated "Given Abbott's intention for ID NOW to be used at the point of care, our sample collection guidance on our product insert has been modified to one hour at room temperature and guides customers to test immediately or store in a clean unused tube for best performance." Review of Abbott ID NOW COVID-19 Instructions for Use (IFU) stated "nasal, throat or nasopharyngeal swab is placed in a clean, unused tube labeled with patient information, and capped tightly at room temperature (15-30C) for up to one (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly

	closed. If greater than one (1) hour delay occurs, dispose of sample. A new sample must be collected for testing." Review of the laboratory's procedure titled "ID NOW COVID-19" stated "If immediate testing is not possible, the nasal, throat or nasopharyngeal swab can be held in its original package at room temperature (15-30 degrees C) for up to two (2) hours prior to testing. If a direct nasal, throat or nasopharyngeal swab specimen will be head longer that two (2) hours, it must be refrigerated at 2-8 degrees C and tested within 24 hours from the time of sample collection." The laboratory's procedure failed to follow the Abbott technical brief and the Abbott ID NOW COVID-19 IFU. Review of patients records revealed the following COVID-19 specimens were collected and received past 1 hour time frame for Abbott ID NOW COVID-19 testing: 1. COVID-19 Patient 1 specimen was collected at 3:39 pm and tested at 4:49 pm on 10/28/2020. 2. COVID-19 Patient 2 specimen was collected at 4:10 pm and tested at 5:39 pm on 10/21/2020. 3. COVID-19 Patient 3 specimen was collected on 12:02 am and tested at 2:10 am on 11/2/2020. 4. COVID-19 Patient 4 specimen was collected on 03:35 am and tested at 05:24 am on 11/2/2020. 5. COVID-19 Patient 5 specimen was collected on 8:46 pm and tested at 10:28 pm on 11/3/2020. 6. COVID-19 Patient 6 specimen was collected on 12:00 am and tested at 2:25 am on 11/7/2020. 7. COVID-19 Patient 7 specimen was collected on 4:00 am and tested at 5:52 am on 11/7/2020. 8. COVID-19 Patient 8 specimen was collected on 1:12 pm and tested at 3:36 pm on 11/9/2020. During an interview on 4/13/2021 at 2:00 pm, Technical Supervisor B confirmed 6,023 COVID-19 tests were perform for Abbott ID NOW from September 2020 to present. During an interview on 4/16/21 at 10:45, Technical Supervisor C acknowledged that some of the specimens were not tested within 1 hour of the collection time.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on record review, observation and interview, the laboratory failed to establish specimen stability requirements for COVID-19 specimens that exceeded the Instructions for Use (IFU) for the Abbott ID NOW COVID-19 from September 23, 2020 to present. Findings Included: Review of the Letter of Authorization for the Abbott ID NOW revealed the Abbott ID NOW was authorized to be performed in a Certificate of Wavier, Certificate of Compliance or Certificate of Accreditation. Review of "ID Now COVID-19" procedure revealed "nasal, throat or nasopharyngeal swab can be held in its original package at room temperature (15-30 Celsius(C)) for up to 2 hours prior to testing. If direct nasal, throat, or nasopharyngeal swab will be held longer than two hours, it must be refrigerated at temperatures of 2-8 degrees Celsius and tested within 24 hours from the time of sample collection." This procedure was approved by Laboratory Director on 12/24/2020. Review of the Abbott

	technical brief dated September 2020 stated the following; "given Abbott's intention for ID NOW to be used at the point of care, our sample collection guidance on our product insert has been modified to one hour at room temperature and guides customers to test immediately or store in a clean unused tube for best performance." Review of Abbott ID NOW COVID-19 IFU stated "nasal, throat or nasopharyngeal swab is placed in a clean, unused tube labeled with patient information, and capped tightly at room temperature (15-30C) for up to one (1) hour prior to testing. Ensure the swab fits securely within the tube and the cap is tightly closed. If greater than one (1) hour delay occurs, dispose of sample. A new sample must be collected for testing." An observation on 4/13/2021 at 12:00 PM of Isotemp refrigerator, in the serology laboratory revealed that COVID-19 specimens were stored in refrigerator at 2-8 degrees C. Refer to D5305 and D5411. During an interview on 4/13/2021 at 2:00 pm, Technical Supervisor B confirmed that 6,023 COVID-19 tests were perform using the Abbott ID NOW from September 2020 to present. During an interview on 4/16/2021 at 10:45am, Technical Supervisor C acknowledged specimen stability requirements were not established for COVID-19 specimen storage and testing past 1 hour timeframe for Abbott ID NOW COVID-19.
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 record review and interview with Technical Supervisor B the laboratory failed to document daily maintenance on the Medtronic HMS and TEG for 1 (June 2020 for the Medtronic HMS and January 2021 for the TEG) out of 2 months (June 2020 and January 2021) reviewed. Findings Included: Review of Medtronic HMS quality control (QC) records revealed that QC was ran on 06/01/20, 06/02/20, 06/08 /20, 06/22/20, and 06/29/20. Daily required maintenance of clean and disinfect was only done on 06/18/20 and 06/23/20. Review of TEG quality control records revealed that QC was ran on 01/05/21, 01/07/21, 01/11/21, 01/12/21, 01/18/21, 01/20/21, 01/22 /21, and 01/28/21. Daily required maintenance of disinfect and clean TEG and area, channel 1 temperature and channel 2 temperature was not documented on 01/28/21. Interview on 04/16/21 at 3:00 PM Technical Supervisor B confirmed that the QC dates and maintenance dates did not correspond.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have corrective policies and procedures for symptomatic COVID-19 patients that received a negative result on the Abbott ID NOW COVID -19. Findings Included: Refer to 5423. Review of patient records revealed the following Centers for Disease Control and Prevention(CDC) defined symptomatic patients receive negative results : 1. Patient #1 was defined by the CDC as symptomatic and tested for COVID-19 by Abbott ID NOW received a negative result on 11/09/2020 2. Patient #2 was defined by the CDC as symptomatic and tested for COVID-19 by Abbott ID NOW received a negative result on 10/28 /2020 3. Patient #3 was defined by the CDC as symptomatic and tested for COVID-19 by Abbott ID NOW received a negative result on 10/21/2020 4. Patient #4 was defined by the CDC as symptomatic and tested for COVID-19 by Abbott ID NOW received a negative result on 11/09/2020 5. Patient #5 was defined by the CDC as symptomatic and tested for COVID-19 by Abbott ID NOW received a negative result on 11/02/2020. 6. Patient #6 was defined by the CDC as COVID-19 symptomatic and in the ICU for COVID-19. Patient # 6 was tested for COVID-19 by Abbott ID NOW received a negative result on 11/3/2020. 7. Patient #7 was defined by the CDC as COVID-19 symptomatic and in the ICU for COVID-19. Patient# 7 was tested for COVID-19 by Abbott ID NOW received a negative result on 2/11/2021. Review of Procedure Manual revealed no confirmatory COVID-19 testing procedure for Abbott ID NOW negative results . During an interview on 4/13/2021 at 2:00 pm, Technical Supervisor B confirmed 6,023 COVID-19 tests were perform for Abbott ID NOW from September 2020 to present. During an interview on 4/15/2021 at 12:00 pm, Technical Supervisor C and testing personnel confirmed the laboratory does not perform confirmatory COVID-19 testing for Abbott ID NOW negative results on specimens from symptomatic patients.