Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2080114	09/30/2021
Name of Provider or Supplier	**Street Address, City, State**	
Women's Center Of Excellence Md Pa	4324 N Mccoll, Mcallen, 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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on surveyor's observations, review of the laboratory's BD (Beckton Dickinson) Affirm VPIII Microbial Identification Test manufacturer's package insert (670160Jaa (04);2019-06), review of a random sampling of patient test log from December of 2020 and April to June of 2021 and interview with the staff it was determined the laboratory failed to follow manufacturer's instructions for sample preparation within specified time frame for 5 of 75 samples reviewed. The findings were: 1. Surveyors

	observations on 09/30/2021 at 1100 hours in the laboratory revealed the laboratory was using the swabs contained in the BD Affirm VPIII Microbial Identification Test Kit for collection of test samples, and that the samples were stored refrigerated prior to sample preparation. 2. Review of the laboratory's BD (Beckton Dickinson) Affirm VPIII Microbial Identification Test manufacturer's package insert (670160JAA(04); 2019-06) revealed under Specimen Storage and Transportation section: "When using the either the BD Affirm VPIII Sample Collection Set or the swabs contained in the BD Affirm VPIII Microbial Identification Test Kit: the total time between placing the sample into the sample collection tube and proceeding with the sample preparation should be no longer than 1 h if the sample is stored at room temperature, or 4 h if the sample is stored at 2 to 8C." 3. Review of a random sampling of patient test log from December of 2020 and April to June of 2021 revealed the following samples exceeded the 4 hours limit from collection to sample preparation: Sample ID: 11-13-83 Collection date/time: 12/29/2020 at 2:55pm Sample preparation date/time: 12/20/2020 at 8:00am Elapsed time: 16 hours 55 minutes Sample ID: 2-19-80 Collection date /time: 12/29/2020 at 5:00pm Sample preparation date/time: 12/20/2020 at 8:00am Elapsed time: 15 hours Sample ID: 2-9-60 Collection date/time: 04/21/2021 at 5: 00pm Sample preparation date/time: 04/22/2021 at 10:26am Elapsed time: 17 hours 26 minutes Sample ID: 12/14/75 Collection date/time: 05/27/2021 at 10:30am Sample preparation date/time: 05/27/2021 at 5:00pm Elapsed time:6 hours 30 minutes Sample ID: 12/3/96 Collection date/time: 06/23/21 at 8:30am Sample preparation date/time: 06 /23/2021 at 12:33am Elapsed time:4 hours 3 minutes Key: ID - Identification (as written on patient test log) 4. In an interview on 09/30/2021 at 1130 hours in the conference room the Technical Consultant (as stated on CMS Form 209 signed by the laboratory director on 9/21/2021) confirmed the above samples were prepared in excess of the 4 hours limit from sample collection.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's BD (Beckton Dickinson) Affirm VPIII Microbial Identification Test manufacturer's package insert (670160JAA(04);2019-06), review of the laboratory's Individualized Quality Control Plan (IQCP), review of the laboratory's quality control (QC) records from February to May of 2021 and interview with the staff it was determined the laboratory failed to perform quality control as required for 2 of 15 instances reviewed. The findings were: 1. Review of the laboratory's BD (Beckton Dickinson) Affirm VPIII Microbial Identification Test manufacturer's package insert revealed: "Quality control requirements must be performed in accordance with applicable local, state, and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures." 2. Review of the laboratory's IQCP revealed the laboratory did establish a modified quality control frequency for the BD Affirm VPIII Microbial Identification Test. IQCP quality control was to be performed every 7 days, with each new lot of reagent, and with every shipment. 3. Review of the laboratory's QC records from February to May of 2021 for the BD Affirm VPIII Microbial Identification Test

	revealed the laboratory was performing QC with every new lot/shipment and every 7 days, except for: a. Week of 02/01/2021 New lot/box opened 02/01/2021 No QC performed; no new lot QC performed Next Quality control performed 02/08/2021. Patients (ID) tested prior to new lot quality control being performed: On 02/01/2021 ID: 11.2.98 ID: 01.6.82 ID: 9.12.01 On 02/02/2021 ID: 7.1.89 ID: 7.25.88 ID: 5.5.68 ID: 3.26.98 On 02/03/2021 ID: 7.31.99 ID: 7.18.97 ID: 1/20/74 On 02/04/2021 ID: 12 /3/67 ID: 5/7/75 ID: 2/25/82 On 02/05/2021 ID: 3/28/90 ID: 3/23/80 ID: 7/06/95 ID: 8 /12/80 b. Week of 03/01/2021 QC performed 03/01/2021 Next QC performed 03/11 /2021 with new lot/box opened Elapsed time from last QC: 10 days Patients (ID) tested after expiration of IQCP quality control 7-day interval: On 03/09/2021 ID: 11 /01/90 ID: 9/3/76 ID: 8/19/65 ID: 10/2/84 On 3/10/2021 ID: 5/7/87 ID: 9/2/81 ID: 11-28-93 Key: ID - Identification (as written on patient test log) 4. In an interview on 09 /30/2021 at 0935 hours in the conference room the Technical Consultant (as stated on CMS Form 209 signed by the laboratory director on 9/21/2021) stated that QC is performed every Monday. This confirmed the findings.
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 personnel competency assessments for 2019, 2020 and 2021 and interview with the staff it was determined the laboratory's technical consultant failed to document the 2020 yearly competency assessment for one of eight testing personnel. The findings were: 1. Review of the laboratory's personnel competency assessments for 2019, 2020 and 2021 revealed Testing Person number six (as stated on CMS Form 209 signed by the laboratory director on 9/21/2021) did not have the yearly competency assessment documented for 2020. 2. The laboratory was asked to provide documentation of Testing Person number six competency assessment for 2020 and no such documentation was provided. 3. In an interview on 09/30/2021 at 0935 hours in the conference room the Technical Consultant (as stated on CMS Form 209 signed by the laboratory director on 9/21/2021) confirmed that Testing Person number six did not have documentation of the yearly competency assessment for 2020.