

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2080140	(X3) Date Survey Completed 09/28/2021
Name of Provider or Supplier Mary Elizabeth Klenz	Street Address, City, State 1400 E Ridge, Road Suite #4, 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	<p>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.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Fern Test twice annually accuracy verification records for 2019, 2020 and 2021, review of the laboratory's policies and procedures and interview with the staff it was determined the laboratory failed to evaluate Fern Test's accuracy verification results for acceptability for 4 of 4 events. The findings were: 1. Review of the laboratory's Fern Test twice annually accuracy verification records for 2019, 2020 and 2021 revealed no evaluation of results for the following testing events: 11/02/2019 05/07/2020 11/09/2020 05/12/2021 2. Review of the laboratory's policies and procedures revealed there were no protocols defined for evaluation of twice annually accuracy verification of the Fern Test. 3. In an interview on 09/28/2021 at 0930 hours in the conference room the Technical Consultant (as</p>

Described on CMS Form 209 signed by the laboratory director on 09/28/2021) stated that there is no policy addressing evaluation of the twice annually accuracy verification for the Fern Test, and confirmed that there was no results' evaluation performed for the above testing events

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 review of the laboratory's BD (Beckton Dickinson) Affirm VPIII Microbial Identification Test manufacturer package insert (670160Jaa(04);2019-06), review of patient test log for 09/28/2021, surveyor's observations and interview with the staff it was determined the laboratory failed to follow manufacturer's instructions for collection of samples for one of one samples observed. The findings were: 1. Review of the BD Affirm VPIII Microbial Identification Test manufacturer package insert Revealed: a. Under Specimen Collection section: "Specimen collection is a critical step. Personnel collecting vaginal fluid specimens should be well-trained to minimize the possibility of inadequate specimens. For specimen collection use only the BD Affirm VPIII Ambient Temperature Transport System, the BD Affirm VPIII Sample Collection Set or the swabs provided in the BD Affirm VPIII Microbial Identification Test Kit." b. Under Vaginal Sample Collection section: "3. Using a sterile swab, obtain a sample from the posterior vaginal fornix." And, "4. Immediately place the swab into the Sample Collection Tube (SCT)." 2. Review of the patient test log for 09/28/2021 revealed one sample (ID:3/25/85) collected at 9:31am awaiting processing. 3. Surveyor's observations on 09/28/2021 at 1022 hours in the laboratory revealed sample ID:3/25/85 stored in the refrigerator in a BD Vacutainer (Red Top) instead of the BD Affirm Sample Collection Tube. 4. In an interview on 09/28/2021 at 10:25 hours in the laboratory the Technical Consultant (as Described on CMS Form 209 signed by the laboratory director on 09/28/2021) confirmed the sample was improperly collected. This confirmed the findings.