

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  17D0923243	<b>(X3) Date Survey Completed</b>  11/28/2023
<b>Name of Provider or Supplier</b>  Stormont Vail Health Ob/Gyn-Lincoln Center,	<b>Street Address, City, State</b>  800 Sw Lincoln St, Topeka, KS	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6036</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413</p> <p>The technical consultant is responsible for the technical and scientific oversight of the laboratory.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the "Affirm Patient Test Log", "Monthly Quality Assurance Checklist", lack of documented corrective action (CA), and interview with technical consultant (TC) #1, the TC failed to provide to provide technical oversight of the laboratory. Findings: 1. Review of the "Affirm Patient Test Log" from 1/1/23 to 10/2/23 revealed 17 patient entries that failed to include 44 required entries. This log requires date of testing, patient name, patient ID number (#), receipt time, lot# with expiration date, negative (neg)quality control (QC) result, Trichomonas result, Gardnerella result, Candida result, positive (pos) QC result, lysis temperature (temp), room temperature, testing personnel (TP). and doctor #. a. No Trichomonas result, Gardnerella result, Candida result, pos QC result, neg QC results for 1 of 5 patient tested on 1/11/23. b. No receipt time for 1 of 7 patients tested on 1/19/23. c. No receipt time for 1 of 2 patients tested on 1/27/23. d. No receipt time for 1 of 5 patients tested on 2/9/23. e. No receipt time for 1 of 9 patients tested on 2/17/23. f. No TP initials or doctor # for 1 of 9 patients on 2/17/23. g. No Trichomonas result, Gardnerella result, Candida result, pos QC result, neg QC results for 1 of 5 patients tested on 4/5/23. h. No Trichomonas result, Gardnerella result, Candida result, pos QC result, neg QC results for 1 of 4 patients tested on 4/24/23. i. No TP initials for 1 of 4 patients tested on 4/28/23. j. No receipt time for 1 of 11 patients tested on 5/9/23. k. No patient ID # for 1 of 2 patients tested on 5/11/23. l. No receipt time for 1 of 4 patients tested on 6/15/23. m. No receipt time for 1 of 3 patients tested on 6/23/23. o. No lysis temp, room temp, TP initials and doctor # for 2 of 7 patients testing on 7/21/23. p. No Trichomonas result, Gardnerella result, Candida result, pos QC result, neg QC results for 1 of 1 patients tested on 9/28/23. q. No Trichomonas result,</p>

Gardnerella result, Candida result, pos QC result, neg QC results for 1 of 2 patients tested on 9/29/23. 2. A total on 17 patient log entries were incomplete from 1/1/23 to 10/2/23. 3. Review of the "Monthly Quality Assurance Checklist" form revealed the following monitored elements: a. Specimens were logged correctly on the laboratory specimen log. b. All lab reports contain correct information. c. All required temperatures were taken. d. Any necessary remedial action was performed and documented. e. All QC/calibrations were performed and accepted before patient test results were reported. f. QC results were examined for possible problems. 4. Review of the completed Monthly Quality Assurance Checklists for January 23 to October 23 revealed: a. January 23: "Yes" as the entry for all monitored elements with no documentation of CA taken, signed by TC#2 on 1/31/23. b. February 23: "Yes" as the entry for all monitored elements with no documentation of CA taken, signed by TC#2 on 2/28/23. c. April 23: "Yes" as the entry for all monitored elements with no documentation of CA taken, signed by TC#2 on 4/28/23. d. May 23: "Yes" as the entry for all monitored elements with no documentation of CA taken, signed by TC#2 on 5/31/23. e. June 23: "Yes" as the entry for all monitored elements with no documentation of CA taken, signed by TC#2 on 6/27/23. f. July 23: "Yes" as the entry for all monitored elements with no documentation of CA taken, signed by TC#2 on 7/31/23. g. September 23: "Yes" as the entry for all monitored elements with no documentation of CA taken, signed by TC#2 on 9/29/23. 5. Interview with TC #1 on 11/28/23 at 10:05 a.m. confirmed, the TC failed to provide to provide technical oversight of the laboratory.