Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0931572	07/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Valley Baptist Physicians Network	1119 Central Blvd, Brownsville, 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
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 IQCP for Sure-Vue Chlamydia, review of manufacturer's instructions, review of patient results in confirmed in interview of facility personnel, the laboratory failed to follow its IQCP to perform quality control testing when opening a kit. The findings were: 1. Review of the laboratory's IQCP reapproved by the laboratory director on 01/01/2018 stated, "Package insert (PI) /instructions for use (IFU) contains system performance data and describes testing principle and procedure, QC recommendations and limitations," and under "Historical Quality Review," Manufacturer QC recommendations: External positive and negative controls should be run on opening each kit." 2. Review of the manufacturer's instructions for the Quidel QuicikVue Chlamydia Test signed by the laboratory director on 09/08/2014 under, "Positive and Negative Quality Control" stated, "The QuickVue Positive and Negative Control solutions should be tested with each new lot or shipment of test materials, once for each 25-test kit and as otherwise required by your laboratory's standard quality control procedures." 3. Review of quality control records from January 1, 2018 to July 25, 2018, the day of the survey revealed the laboratory tested external quality control (negative and positive) on the following dates: 01-26-2018 02-05-2018 03-02-2018 04-02-2018 05-15-2018 06-07-2018 4.

	Review of patient result logs from January 26, 2018 to July 25, 2018 revealed the following patients were tested when quality control had not been performed (see patient alias report): Last 3 digits of Patient ID: 302 811 931 233 652 139 660 956 498 765 595 134 984 687 156 011 157 874 846 637 910 086 796 988 426 805 900 902 221 109 634 919 609 527 438 148 995 251 078 737 845 273 303 682 278 029 659 062 309 464 937 294 972 905 631 541 325 324 813 200 250 302 5. The above findings were confirmed in interview with testing personnel one (as listed on Form CMS-209) on July 25, 2018 at 14:30 hours in the office. She confirmed the laboratory was testing each new lot and shipment not every 25-test kits. Key: IQCP - Individualized Quality Control PlanCMS - Centers for Medicare and Medicaid Services