Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 42D0250784	**(X3) Date Survey Completed** 02/21/2019
Name of Provider or Supplier Parkwood Pediatric Group	**Street Address, City, State** 1483 Tobias Gadson Blvd, Suite 109, Charleston, SC	
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**
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on laboratory quality control records, lack of documentation, and testing personnel interview, the laboratory failed to perform quality control checks for each batch, lot number and shipment of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response before, or concurrent with, initial use for twenty four out of twenty four months reviewed from 2017 to 2018 (January 2017 through December 2018). Findings include: 1. Review of laboratory quality control records revealed that end user quality control for each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response was not being performed for the Uricult CLED/MB test media. 2. Records of quality control testing or an acceptable Individualized Quality Control Plan (IQCP) for the urine culture test was unavailable for review for twenty four out of twenty four months reviewed from 2017 to 2018 (January 2017 through December 2018). 3. Testing personnel confirmed during an onsite interview on 02/21/2019 at 1:30pm that the laboratory had failed to perform quality control testing or establish an acceptable IQCP for urine culture testing.