Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0888484	03/14/2018
Name of Provider or Supplier	**Street Address, City, State**	
Psmg-Red Rose Pediatrics	233 College Avenue, Lancaster, PA	

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
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of media quality control records and interview with the Clinical Supervisor, the laboratory failed to check each batch of Uricult CLED/EMB media used for urine cultures, for sterility and ability to support growth in 2017 to the date of survey. Findings Include: 1. On the date of survey, 03/14/2018, after review of media quality control, it was discovered that the laboratory did not perform quality control on the Uricult CLED/ EMB media. 2. The laboratory reports out growth or no growth and in 2017, about 600 specimen were reported. 3. The Clinical Supervisor confirmed the findings above on 03/04/2018 2:00 PM.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to

	identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of College of American Pathologist (CAP) proficiency testing (PT) records and interview with Clinical Supervisor, the Laboratory Director failed to ensure that all proficiency testing reports received, identified problems that require corrective action (CA) from 2016 and 2017. Findings include: 1. On the day of survey, 03/14/2018, it was discovered the laboratory did not document the corrective actions for scores 80% and below for Bacteriology CAP PT events in 2016 and 2017. CAP 2016 Event #1 - 0% for Bacteriology CAP 2016 Event #2 - 80% for Bacteriology CAP 2016 Event #3 - 80% for Bacteriology CAP 2017 Event #3 - 80% for Bacteriology 2. Clinical Supersiover confirmed the findings above on 03/14/2018 around 1:30 PM.
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on, the review of laboratory records and interview with Clinical Supervisor, the Laboratory Director failed to ensure that the quality assessment programs are maintained and documented to assure the quality of laboratory services provided from 2016 to the date of survey. Findings: 1) On the day of survey 03/14/2018, after review of records, it was revealed the laboratory's failed to document quality assessment activities for the pre-analytic, analytic and post analytic phases of the laboratory in 2016 and 2017. 2) The Clinical Supervisor confirmed the findings above on 3/14/2018 around 2:45 PM.