Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0679494	02/26/2020
Name of Provider or Supplier	**Street Address, City, State**	
Goppert-Trinity Family Care	6675 Holmes Rd, Ste 360, Kansas City, MO	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on the lack of personnel competency policies and procedures and interview with the laboratory manager, the laboratory failed to establish written policies and procedures to assess employee (testing personnel) competency. Findings: 1. Review of laboratory policies and procedures revealed the laboratory did not establish written personnel policies and procedures to assess testing personnel competency. 2. Interview with the laboratory manager on February 26, 2020 at 11:00 AM confirmed the laboratory failed to establish written policies and procedures to assess testing personnel competency.
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 proficiency testing (PT) records and interview with testing personnel #1, the laboratory director failed to ensure two of three PT reports for 2018 and three of three PT reports for 2019 were reviewed by appropriate staff and identify problems that require corrective action. Findings: 1. The laboratory did not have documentation to show appropriate staff (technical consultant and/ or laboratory director) reviewed the second and third PT events in 2018 and first, second and third PT events in 2019. 2. No documentation was found to show the laboratory identified failed results for specimen CM-2 for first PT event in 2019 and specimen CM-11 for second PT event in 2019. (Refer to D6019) 3. Interview with testing personnel #`1 on February 26, 2020 at 11:00 AM confirmed the laboratory director failed to ensure appropriate staff reviewed PT reports and identify problems requiring corrective action.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on the lack of an approved corrective action plan for proficiency testing (PT) results, review of PT records for 2018 and 2019 and interview with the laboratory manager, the laboratory director failed to establish a corrective action plan for PT results found to be unacceptable or unsatisfactory. Findings: 1. The laboratory did not have a corrective action plan for PT results found to be unacceptable. 2. The laboratory received unacceptable results for specimen CM-2 for first event in 2019 and specimen CM-11 for second event in 2019. 3. Interview with the laboratory manager on February 26, 2020 at 11:00 AM confirmed the laboratory director failed to ensure an approved corrective action plan was followed for PT results found to be unacceptable or unsatisfactory.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on the lack of performance/competency evaluations and interview with the laboratory manager, the technical consultant failed to evaluate and document the performance for one of one testing personnel performing moderate complexity clinical microscopy testing for 2018, 2019 and to date February 26, 2020. Findings: 1. The laboratory did not have documentation to show the technical consultant evaluated and documented the performance/competency for one testing personnel performing moderate complexity urine microscopic examinations, potassium hydroxide (KOH) and wet mount preparation procedures for 2018, 2019 and to date February 26, 2020.

	2. Interview with the laboratory manager on February 26, 2020 at 11:00 AM confirmed the technical consultant failed to evaluate and document the performance /competency for one testing personnel performing clinical microscopy procedures.