Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0441988	03/19/2019
Name of Provider or Supplier	**Street Address, City, State**	
Regional Primary Care, Inc	150 S Mt Auburn Rd, Ste 418, Cape Girardeau, 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 review of laboratory policies and interview with the technical supervisor, the laboratory failed to establish a written policy to assess personnel competency. Findings: 1. The laboratory did not have a personnel competency assessment policy. 2. Interview with the technical supervisor on March 19, 2019 confirmed the laboratory did not establish a policy to assess personnel competency.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, urinalysis procedure manual and interview with the general supervisor, the laboratory failed to follow manufacturer's instructions for preparing urine samples for microscopic examination. Findings: 1. The manufacturer's instructions states," Fill the KOVA tube to 12 ml " and "centrifuge at 400 RCF (1500 RPM) for five minutes." 2. The procedure manual states, "Centrifuge 12 mls of a mixed, freshly voided urine in a KOVA tube for 2 minutes

	and 20 seconds at 3350 RPM." 3. Interview on March 19, 2019 at 11:45 AM, the general supervisor said the laboratory has performed the KOVA system procedure for obtaining urine sediment (microscopic examination) since the 1990's. The general supervisor said the centrifuge in use for preparing urine for microscopic examination has been in service for four years and operated at a speed of 3350 RPM. The interview confirmed the laboratory failed to follow the KOVA systems manufacturer's instructions for preparing urine samples for microscopic examination.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of two of two hematology test reports from December 2018, hematology procedure manual and interview with the general supervisor, the laboratory failed to ensure pertinent patient normal were available for interpretation. Findings: 1. The differences between normal values on patient test reports and those included in the approved procedure manual and currently in use are as follows: Normal values stated on female patient hematology test report reported December 12, 2018: WBC (white blood cells) 4.8-10.8 RBC (red blood cells) 4.00-5.50 HGB (hemoglobin) 12.0-16.0 HCT (hematocrit) 37.0-47.0 MCV (mean corpuscular volume) 80-96 MCH (mean corpuscular hemoglobin) 26-34 MCHC (mean corpuscular hemoglobin concentration) 31.0- 37.0 PLT (platelets) 130-430 Gran % 37.0-92.0 Lymph % 10-58.5 Mid % 0.1-24 Normal values stated on male patient hematology test report reported December 17, 2018: WBC 4.8-10.8 RBC 4.10-6.10 HGB 14.0-18.0 HCT 42.0-52.0 MCV 80-96 MCH 26.0-34.0 MCHC 31.0- 37.0 PLT 130-430 Gran % 37.0-92.0 Lymph % 10-58.5 Mid % 0.1-24 Normal values for male (M) and female (F) stated in the hematology procedure manual approved September 13,2018 WBC 4.7-10.3 M/F RBC 4.03-5.46 M/F HGB 12.4-16.9 M/F HCT 36.6-48.3 M/F MCV 81.5-96.80 M/F MCH 27.5-33.10 M/F MCHC 32.40-35.70 M/F PLT 165.00-385.00 M/F Gran % 43.50-78.90 M/F Lymph % 12.70-47.80 M/F Mid % 6.3-14.00 M/F 2. Interview with general supervisor on March 19, 2019 at 11:45 AM confirmed the normal values stated on patient test reports differed from those stated in the approved hematology procedure manual.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on review of performance (competency) evaluations for 2018 and interview with the technical supervisor, the technical supervisor failed to evaluate and document the performance for two of two testing personnel responsible for high complexity

	hematology testing. Findings: 1. Review of competency evaluations for 2018 showed no documentation two testing personnel were evaluated for performing high complexity manual white blood cell (WBC) differentials and red blood cell (RBC) morphology. 2. Interview on March 19, 2019 at 11:45 AM the technical supervisor confirmed the laboratory did not include competency evaluation for testing personnel performing high complexity manual differentials.