Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0406030	10/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Centracare Richmond	130 First St Ne, Richmond, MN	

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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: . Based on review of Center for Medicare and Medicaid Services reports, American Proficiency Institute proficiency testing reports, and voicemail communication with Testing Personnel, the laboratory failed to successfully participate in proficiency testing (PT) for White Blood Cell Differential testing under the specialty of Hematology. Findings are as follows: D2121 - the laboratory failed to obtain a PT score for White Blood Cell Differential of at least 80 percent D2123 - the laboratory failed to participate in the 2018 3rd Hematology testing event D2130 - the laboratory failed to achieve successful PT performance for White Blood Cell Differential testing in two of three consecutive PT events

D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: . Based on review of proficiency testing (PT) reports from the American Proficiency Institute (API) and voicemail communication with Testing Personnel, the laboratory failed to obtain a PT score for White Blood Cell Differential of at least 80 percent which resulted in unsatisfactory performance for the analyte. Per API reports, unsatisfactory White Blood Cell Differential PT performance was obtained in the following API events. -2018 3rd event 0% -2019 2nd event 0% In a voicemail received at 3:30 p.m. on 10/18/19, the Testing Personnel indicated the 2019 2nd event PT failure was due to incorrect data entry.
D2123	HEMATOLOGY CFR(s): 493.851(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: . Based on a review of proficiency testing (PT) reports from the American Proficiency Institute (API), the laboratory failed to participate in one PT event for White Blood Cell differential testing. Findings are as follows: The laboratory failed to participate in White Blood Cell differential PT for the 2018 third Hematology event. Failure to participate in the testing event resulted in unsatisfactory performance for the analyte.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: . Based on review of proficiency testing (PT) reports from the American Proficiency Institute (API), the laboratory failed to achieve successful PT performance for White Blood Cell Differential testing in two out of three consecutive PT events. Findings are as follows: The laboratory received unsatisfactory scores for White Blood Cell Differential testing in two out of three consecutive PT events which constitutes unsuccessful performance. PT reports from API listed the following unsatisfactory White Blood Cell Differential scores. -2018 3rd event 0% -2019 2nd event 0%