

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0998952	(X3) Date Survey Completed 10/02/2018
Name of Provider or Supplier City Medical Pc	Street Address, City, State 13636 Dix Toledo Road, Southgate, MI	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on procedure review, record review, and interview, the laboratory failed to follow standard operating procedures to document corrective action taken when refrigerator temperatures are outside the stated range for nine (June 22, 25-29 and July 27, 30-31) of 62 days reviewed in June and July of 2018 to ensure reliable hematology and chemistry control material acceptability. Findings include: 1. On October 2, 2018 at approximately 10:55 AM, procedure review revealed "out of range temperatures must be adjusted and documented". 2. On October 2, 2018 at 11:38 AM, record review of the temperature recordings revealed for the refrigerator (35-46 degree C) nine (June 22, 25-29 and July 27, 30-31) of 62 days reviewed in June and July of 2018 there was no documentation of the corrective action taken for the temperatures recorded that exceeded the stated range. 3. During the interview on October 2, 2018 at 11:38 AM, technical consultant #2 as listed on the CMS-209 confirmed no corrective action was taken for the temperatures that exceeded the stated range. ***Repeat Deficiency from February 26, 2013 survey***</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's</p>

instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

. Based on observation, record review, and interview, the laboratory failed to monitor and document the freezer temperature for 24 (September 2016 to September 2018) of 24 months of operation to ensure reliable chemistry control material. Findings include: 1. During a tour of the laboratory on October 2, 2018 at 9:45 AM, the surveyor observed the Danby freezer stored the liquid immunoassay quality control material used for the routine chemistry and endocrinology testing. 2. On October 2, 2018 at 11:38 AM, record review of the "Temperature/Humidity Chart" revealed the laboratory did not monitor and document the daily freezer temperatures for 24 (September 2016 to September 2018) of 24 months of operation. 3. During the interview on October 2, 2018 at 11:38 AM, technical consultant #2 as listed on the CMS-209 confirmed the freezer was not monitored and temperatures documented daily. ***Repeat Deficiency from June 8, 2016 survey***

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the laboratory failed to perform and document the hematology Cell-Dyn 1800 analyzer maintenance for 1) the weekly auto clean and clean aspiration probe exterior for three (September 2016, March and October 2017) of 24 months, and 2) the monthly rinse lyse inlet line and rinse reagent inlet lines for 12 (September - November 2016, January-July and October 2017, and February 2018) of 24 months, and 3) the semi-annual clean printer for three (October 2016, April and October 2017) of four semi-annual checks reviewed. Findings include: 1. On October 2, 2018 at 11:47 AM, record review of the "Cell-Dyn 1800 Maintenance Log" revealed the laboratory did not perform and document the required tasks as listed on the maintenance log as follows: a. weekly - three (September 2016, March and October 2017) of 24 months b. monthly - 12 (September - November 2016, January-July and October 2017, and February 2018) of 24 months c. semi-annual - three (October 2016, April and October 2017) of four December 12, 2. During the interview on October 2, 2018 at 11:47 AM, technical consultant #2 as listed on the CMS-209 confirmed the laboratory did not perform and document the required maintenance tasks.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--
(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through

493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the laboratory failed to perform the chemistry and endocrinology quality control each day of patient testing for two (#8 - #9) of nine patient charts audited. Findings include: 1. On October 2, 2018 at 12:30 PM, record review for two (#8 - #9) of nine patient charts audited revealed the laboratory did not run at least two different levels of controls each day of patient testing as follows: a. chemistry testing - patient #8 and #9 for prostate specific antigen (PSA) b. endocrinology testing - patient #9 for thyroid stimulating hormone (TSH) 2. During the interview on October 2, 2018 at 12:30 PM, technical consultant #2 as listed on the CMS-209 confirmed two different levels of controls had not been performed on the day of patient testing. ***Repeat Deficiency from July 9, 2014 and June 8, 2016 surveys***