Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D1086030	04/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Memphis Primary Care Specialists	3960 Knight Arnold Road Suite 102, Memphis, TN	

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
D2003	ENROLLMENT CFR(s): 493.801(a)(2)(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must establish and maintain the accuracy of its testing procedures, in accordance with 493.1236(c)(1) This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the laboratory test menu records, the procedure manual, the lack of proficiency testing records and interview with the laboratory liaison, the laboratory failed to establish and maintain the accuracy of its testing procedures for the toxicology specialty, urine drug screen. The findings include: 1) Observation on the laboratory on April 5, 2018 at 11:55 am revealed the BPC BioSed Global 240 Automatic Analyzer in use for patient testing urine drug screen. 2) Review of the laboratory test menu records revealed the following urine drug screen analytes: amphetamines (AMP), barbiturates (BAR), benzodiazepine (BNZ), cocaine (COC), methadone (MTD), oxycodone (OXY), opiate (OPI), buprenorphine (BUP), ethanol (ETO), marijuana (CANN), methylenedioxy-methamphetamine (XTC), fentanyl (FEN), along with routine chemistry analytes: oxidants (OXD), specific gravity (SG), pH. 3) Review of the laboratory procedure manual revealed no procedure was established and followed to ensure accuracy of its testing procedures for the UDS, at least twice per year. 4) Review revealed no proficiency testing records available 5) Interview on April 5, 2018 at 12:10 p.m. with the laboratory liaison confirmed no enrollment in proficiency testing for the UDS and no procedure for twice per year accuracy.
D5305	TEST REQUEST CFR(s): 493.1241(c) The laboratory must ensure the test requisition solicits the following information: (1)

	The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (2) The patient's name or unique patient identifier. (3) The sex and age or date of birth of the patient. (4) The test(s) to be performed. (5) The source of the specimen, when appropriate. (6) The date and, if appropriate, time of specimen collection. (7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on lack of the test request and interview with the laboratory liaison, the laboratory failed to the test request, in 2018. The findings include: 1) Based on lack of test request records revealed there were no test request for the urine drug screen. 2) Interview on April 5, 2018 at 1: 10 p.m. with the laboratory liaison confirmed there were no urine drug screen request, the samples are received with no request from the provider.
D5405	PROCEDURE MANUAL CFR(s): 493.1251(c) Manufacturer's test system instructions or operator manuals may be used, when applicable, to meet the requirements of paragraphs (b)(1) through (b)(12) of this section. Any of the items under paragraphs (b)(1) through (b)(12) of this section not provided by the manufacturer must be provided by the laboratory. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of available laboratory records and interview with the laboratory liaison, the laboratory failed to maintain a copy of the manufacturer's test system instructions or operator manual. The findings include: 1) Observation of the laboratory revealed the BPC BioSed Global 240 Automated Analyzer in use for patient testing. 2) Review of available laboratory records revealed the BPC BioSed Global 240 Automated Analyzer operator's manual or system instructions were not included. 3) Interview on April 5, 2018 at 12:15 p.m. with the laboratory liaison confirmed the operator's manual or system instructions were not available or maintain.
D5425	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(3) The laboratory must determine the test system's calibration procedures and control procedures based upon the performance specifications verified or established under paragraph (b)(1) or (b)(2) of this section. This STANDARD is not met as evidenced by: Based on review of the establishment and verification of performance specifications records, a lack of the manufacturer's instructions and interview with the laboratory

	liaison, the laboratory failed to establish the Global 240 instrument calibration frequency, type, number, and concentration of calibration and control materials. The findings include: 1) Review of the Global 240 establishment and verification of performance specification records revealed the calibration frequency, type, number, concentration of calibration and control materials were not included for the urine drug screen (UDS) panel. The UDS panel included the following analytes: AMP, BAR, BNZ, COC, MTD, OXY, OPI, BUP, XTC, FEN, ETO, OXD, CANN. 2) The Global 240 instrument manufacturer's instructions / operator's manual was not available for review of calibration information. The Global 240 Automated Analyzer test system is not subject to Food and Drug Administration (FDA) clearance or approval. The laboratory could not provide FDA approval information/ documentation. 3) Interview on April 5, 2018 at 12:10 p.m. with the laboratory liaison confirmed the Global 240 operator's manual was not in the laboratory and that the calibration frequency, type, number, and concentration of calibration and control materials followed the manufacturer's instructions, and were not established with the installation of the instrument.