DEPARTMENT OF HEALTH AND HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 02/18/2011
FORM APPROVED
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	52D0397477	A. BUILDING _____ B. WING _____	02/10/2011

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF WI, INC	302 N JACKSON ST MILWAUKEE, WI 53202

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
D6021	493.1407(e)(5) DIRECTOR RESPONSIBILITIES The laboratory director must assure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Surveyor: 14023 Based on surveyor review of patient test logs, reference laboratory reports, corrective action records and interview with the technical consultant, the laboratory director did not evaluate corrective action taken for discrepant Rh results that occurred on September 28, 2010. Four of 41 patients showed discrepant Rh results between their laboratory and the reference laboratory. Findings include: 1. Review of patient test logs dated September 28, 2010 shows 4 of 41 patients tested were reported as Rh negative. 2. Review of reference laboratory results for the four patients reported as Rh negative, using the Eldon Card test system, show the reference laboratory results were reported as Rh positive for the same four patients. 3. Review of corrective action documentation dated September 28, 2010 shows that the Eldon Card system (lot #10041, expiration date 2012-01) used for Rh testing was discontinued on September 28, 2010 due to discrepant patient test results. 4. Evaluation of this incident by the laboratory director is not documented. 5. Interview with the technical consultant on [redacted]	D6021	Any lab discrepancy that requires an improvement plan such as the one mentioned during the review process on Feb 10th, 2011, will require the laboratory director to sign off on the improvement plan. (See attached improvement plan form). The improvement plan will indicate the problem, the plan of action to rectify the problem, the person responsible and the timeline. These improvement plans will be kept in the lab binders. Lab discrepancies will be monitored by PPWI's Laboratory Technical Consultant and Clinical Coordinator. These discrepancies will be discussed at the AB Management staff meetings (which meets twice a month) and also monthly center staff meetings. The Lab Director will be made aware of the situation within 48 hours and will sign off on the Improvement plan within 1-2 weeks of being developed. POC OL QL 3/7/11	2/28/11 and on-going

LABORATORY DIRECTOR'S OR [redacted] SIGNATURE [redacted] TITLE (X6) DATE 3/2/11

Any deficiency statement endi[redacted] which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient p[redacted] Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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D6021	Continued From page 1 February 10, 2011 at 1:30 PM confirmed that the laboratory director did not review or evaluate the corrective action documentation for this incident.	D6021		

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	52D0397477	A. BUILDING _____ B. WING _____	03/20/2013

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D 000	INITIAL COMMENTS Surveyor: 27818 Planned Parenthood of Wisconsin Inc laboratory was found in compliance with 42 CFR Part 493, Requirements for Laboratories, as a result of the onsite survey of March 20, 2013.	D 000		

LA[redacted]UPPLIER REPRESENTATIVE'S SIGNATURE | TITLE: Vice President of Patient Services | (X6) DATE: 3/20/13

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	52D0397477	A. BUILDING _____ B. WING _____	01/21/2015

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D5209 110M 120M 130M 510M	493.1235 PERSONNEL COMPETENCY ASSESSMENT POLICIES 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: Surveyor: 14023 Based on surveyor review of the laboratory Quality Assessment (QA) procedure and interview with the Vice President of Patient Services, the laboratory does not have a written procedure for evaluating testing personnel competency that includes the frequency of evaluations and all required elements. Findings include: 1. Review of the laboratory QA procedure shows the current procedure does not include step by step instructions for evaluating competency of testing personnel that includes the frequency of evaluations and all required elements of competency. 2. Interview with the Vice President of Patient Services on January 21, 2015 at 11:35 AM confirmed the current QA procedure does not include step by step instructions for evaluating competency of testing personnel.	D5209		4/1/15

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 03/02/2015

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D2009	493.801(b)(1) TESTING OF PROFICIENCY TESTING SAMPLES The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records from the Madison location of the laboratory and interview with the technical consultant, the laboratory director has not attested to the routine integration of the PT samples into the patient workload using the laboratory's routine methods. Findings include: 1. Review of PT records for 2016 show the attestation statements for the Madison location of the laboratory have not been signed by the laboratory director. 2. Interview with the technical consultant on March 29, 2017 at 1:45 PM confirmed the signature on the attestation forms is not that of the laboratory director or the technical consultant.	D2009		6/21/17
D5403 510M	493.1251(b) PROCEDURE MANUAL The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in §493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results.	D5403		6/21/17

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D5403	Continued From page 1 (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in §493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor review of the manufacturer's instructions and the procedure for Eldon Card RhD (Rhesus D antigen), and interview with the technical consultant, the laboratory procedure does not include the manufacturer's instructions to not open the storage bag for the Eldon Cards (EldonBag) at less than 64 degrees Fahrenheit. Findings include: 1. The manufacturer's instructions state the EldonBag should not be opened if the temperature is below 64 degrees Fahrenheit.	D5403		

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D5403	Continued From page 2 2. Review of the Eldon Card RhD procedure shows no restrictions for opening the EldonBag. 3. Interview with the technical consultant on March 29, 2017 at 2:45 PM confirms the procedure does not include the manufacturer's restrictions for opening the EldonBag.	D5403		
D5413 510M	493.1252(b) TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT 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 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 surveyor review of the manufacturer instructions and laboratory records, and interview with the technical consultant, the laboratory does not document the room temperature to ensure storage requirements for Eldon RhD (Rhesus D Antigen) test are met. Findings include: 1. The manufacturer's instructions for the Eldon RhD cards include directions to store the cards between 41 - 99 degrees Fahrenheit and not to	D5413		6/21/17

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D5413	Continued From page 3 open the EldonBag if the temperature is below 64 degrees Fahrenheit. 2. Review of laboratory records shows no documented room temperature records for the laboratory. 3. Interview with the technical consultant on March 29, 2017 at 2:45 PM confirmed room temperatures are not documented in the area where Eldon Cards are stored and used.	D5413		

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