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

PRINTED: 09/26/2019 FORM APPROVED OMB NO. 0938-0391

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION A. BUILDING | | | (X3) DATE SURVEY COMPLETED | |
|---|---|--|--|---|---|-------------------------------|--|
| | | 21D0216329 | B. WING | | | 09/20/2019 | |
| NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD-MD ANNAPOLIS HEALTH CENTER | | | | STREET ADDRESS, CITY, STATE, ZIP CO 929 WEST STREET STE 305 ANNAPOLIS, MD 21403 | DDE | | |
| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | | ID PREFII TAG | X (EACH CORRECTIVE ACTION S | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIAT DEFICIENCY) | | |
| D 000 | INITIAL COMMENT | -S | D0 | 00 | | | |
| D2009 | the following location Planned Parenthoo 8579 Commerce Di Suite 102 Easton, MD 21601 | d : FICIENCY TESTING | D20 | 09 | | | |
| | and the laboratory of routine integration of workload using the laboratory of this STANDARD is Based on proficient and interview with the assurance, the laboratesting person signer attesting that PT speway as patient samp Findings: 1. A review of Rh P showed that the test attestation statement 2018. | ratory failed to ensure that the d PT attestation statements, ecimens were run in the same | | | | | |
| D2015 | the director of quality | y assurance confirmed that ments were not signed by the event listed above. | D201 | 5 | | | |
| ABORAT | preparation, process | ust document the handling, ing, examination, and each d reporting of results for all | | | | (X6) DATE | |

Any defic other safeguards provide sufficient protection to the patients. (See instructions.) 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.

FORM CMS-2567(02-99) Previous Versions Obsolete

Event ID; PMQH11

Facility ID: MD900022

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| | proficiency testing similarinal a copy of a the proficiency testing by the laboratory to results including the provided by the PT analyst and the laboratory to that proficiency testing ame manner as partial minimum of two year proficiency testing e (6) PT is required for examination used patient testing during This STANDARD is Based on proficience and interview with the assurance, the laboratory of all PT record minimum of two year testing event. Findings: 1. A review of Rh Promainer as patient sareview at the time of 2. The PT report for record PT results for at the time of the sur 2018 (Nonchemistry 3. During an interview the director of quality the attestation works from the PT events 1 | camples. The laboratory must all records, including a copy of any program report forms used record proficiency testing attestation statement program, signed by the pratory director, documenting ing samples were tested in the attent specimens, for a ars from the date of the event. If only the test system, assay, if as the primary method for gethe PT event. If only the test system, assay, if as the primary method for gethe PT event. If only the test system, assay, if as the primary method for gethe PT event. If only the test system, assay, if as the primary method for gethe PT event. If only the test system, assay, if as the primary method for gethe PT event. If only the test system, assay, if as the primary method for gethe PT event. If only the test system, assay, if as the primary method for gethe PT event. If records from 8 PT events howed that for event Q3 of the attestation worksheet, eximens were run in the same amples was not available for the survey; and from used by the laboratory to reach the survey; and gethe survey for Q3 of 2017 and Q1 of the survey for Q3 of 2017 and Q1 of the survey are confirmed that sheet and PT report forms isted above were not PT records reviewed. | D20 | | | | |
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| (X4) ID PREFIX TAG | (EACH DEFICIENCY | TEMENT OF DEFICIENCIES 'MUST BE PRECEDED BY FULL SC IDENTIFYING INFORMATION) | ID PREFI TAG | | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD ROSS-REFERENCED TO THE APPROPI DEFICIENCY) | BE | (X5) COMPLETION DATE |
| | INSTRUMENTS, RICFR(s): 493.1252(c) Reagents, solutions materials, calibratio supplies, as appropindicate the followin (1) Identity and whe concentration. (2) Storage requiren (3) Preparation and (4) Other pertinent in use. This STANDARD is Based on observati laboratory staff, the the Panoscreen conlabeled with the date Findings: 1. During a tour of twas observed that the Panoscreen Reage the laboratory refrige the date that they we 2. During an interviet the director of quality | EAGENT c, culture media, control n materials, and other riate, must be labeled to g: n significant, titer, strength or ments. expiration dates. nformation required for proper on and interview with the laboratory did not ensure that trols for Rh testing were that they were put in to use. the laboratory at 9:15 AM, it ne opened and in use nt Red Blood Cell" controls in the put in to use ew on 9/20/19 at 11:00 AM, y assurance confirmed that the were not labeled with the | D54 | 15 | DEFICIENCY) | | |
| | | | | | | | |



330 N. Howard Street Baltimore, MD 21201 (410) 576-1400 www.plannedparenthood.org/maryland

Planned Parenthood of Maryland

September 30, 2019

Dear

I was great to work with you on the survey of the Easton Health Center. We appreciate the time you spent and the informative feedback that was provided. I appreciate you looking into the options for proficiency testing attestation.

I have attached the completed CMS-2567 and the evidence of plan of correction of the cited deficiencies. Please review the enclosed materials and contact me if you have any questions.

Kindly,



CLIA Survey: Plan of Corrections

D2009

1. No patients were found to have been affected by this deficiency.

2. No patients were identified as having the potential to have been affected.

3. A review of the CLIA requirements and the PPM policy of retention of original attestation statement

was done with all clinical staff on a training on Monday, September 23rd. Staff were reminded to sign the original form which is used to document the results of the proficiency test. Staff were also reminded to

retain all the original documents in the binder with each testing event. Staff will also be reminded of the

documentation and retention requirements by email prior to each testing event.

4. The proficiency testing documentation will be monitored after each testing cycle to ensure

compliance.

Completion Date: September 23, 2019.

D2015

1. No patients were found to have been affected by this deficiency.

2. No patients were identified as having the potential to have been affected.

3. A review of the CLIA requirements and the PPM policy of retention of original attestation statement was done with all clinical staff on a training on Monday, September 23rd. Staff were reminded to retain

all the original documents in the binder with each testing event. Staff will also be reminded of retention

requirements by email prior to each testing event.

4. The proficiency testing documentation will be monitored after each testing cycle to ensure

compliance.

Completion Date: September 23, 2019.

D5415

- 1. No patients were found to have been affected by this deficiency. The controls were brand new and opened the day of the review. The controls tested as expected for each reagent.
- 2. No patients were identified as having the potential to have been affected.
- 3. A review of the CLIA requirements and the PPM policy of dating all reagents when opened was done with all clinical staff on a training on Monday, September 23rd. Staff were reminded to date any laboratory controls when opened.
- 4. PPM RQM staff will perform an onsite review annually, at minimum to ensure all reagents are marked with an open date.

Completion Date: September 23, 2019.