PRINTED: 12/07/2015
FORM APPROVED

Agency for Health Care Administration

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	LB26933361	A. BUILDING: _____ B. WING _____	12/03/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF SOUTHWEST & (	8068 N 56TH STREET TAMPA, FL 33617

(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) COMPLETE DATE
L 000	Initial Comments A relicensure survey was conducted on [redacted] Planned Parenthood of Southwest & Central Florida (800006706) clinical laboratory had deficiencies at the time of the survey.	L 000		
L2515	59A-7.026(2)(a) PARTICIPATION IN PROFICIENCY TESTING (2) Testing of proficiency testing samples. (a) The samples must be examined or tested with the laboratory's patient workload by personnel who perform the testing in the laboratory, using the laboratory's methods established for patient testing. The individual testing or examining the samples and the laboratory director must attest to the integration of the samples into the patient workload using the laboratory's methods established for patient testing. This Statute or Rule is not met as evidenced by: Based on review of proficiency records, policies and procedures manual, and interview with the Clinical Manager, the Laboratory Director or a qualified Designee did not sign the Proficiency Testing Performance Evaluation forms for 5 out of 5 testing events and the Testing Person did not sign 1 out of 5 testing events for the subspecialty Findings included: Review of Proficiency testing records for 2014 and 2015 from API (American Proficiency Institute) testing events revealed: -For 2014, the Laboratory Director or Designee	L2515	This did not have an impact on patients because the results of API Proficiency testing results were correct. Effective / / the Laboratory Director has reviewed and verified API proficiency results for 2014 and 2015(attached) and moving forward will continue to review and sign verifying API proficiency results. This will be tracked by the director of quality and reported during the quarterly CQRM meeting to ensure compliance.	11/19/15

Plan Accepted by Ricardo Ruas 12/18/15

AH Form 3020-0001

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE — TITLE: Lab Director — (X6) DATE: 12/15/15

STATE FORM 62LL11 If continuation sheet 1 of 8

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	LB28933351	A. BUILDING: _____ B. WING _____	12/03/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF SOUTHWEST & (	8068 N 56TH STREET TAMPA, FL 33617

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L2515	Continued From page 1 did not sign the Proficiency Testing Performance Evaluation forms for all three testing events for API. The Testing Person did not sign the Attestation Statement for the 2nd Testing event of 2014. -For 2015, the Laboratory Director or Designee did not sign the Proficiency Testing Performance Evaluation forms for both testing events for API. Review of the Laboratory Policies and Procedures Manual revised 2014 documented "The Lab Director must review and sign the proficiency test results within 30 days of receipt." An interview with the Clinical Manager on at 11:00 a.m. verified that the Laboratory Director failed to sign Proficiency Testing Performance Evaluation forms for 5 out of 5 testing events in 2014 and 2015. The Clinical Manager also verified the missing signature of the Testing Person for the 2nd Testing event of 2014.	L2515		
L2909	59A-7.029(2)(c) GENERAL QUALITY CONTROL REQUIREMENT All equipment and supplies shall be in good working order, checked and calibrated for the proper performance of tests and services offered in accordance with this rule and CLIA requirements. The laboratory must, at a minimum, follow the manufacturers' recommendations and instructions for equipment operation and document all such activities required for maintenance and operation of such equipment.	L2909	Patients were not affected because upon date of service (___/ /__)no adjustments were needed. Equipment maintainance policy will be adjusted to reflect that all new equipment must be serviced and/or tested prior to use.	12/30/15

From: / / 08:19 #104 P /

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	LB26933351	A. BUILDING: _____ B. WING _____	12/03/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD OF SOUTHWEST & C	8068 N 56TH STREET TAMPA, FL 33617

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L2909	Continued From page 2 This Statute or Rule is not met as evidenced by: Based on observation, record review, and interview with Clinical Manager the laboratory failed to follow the manufacturer's instructions to perform professional annual service on two of the M280 Unico Microscopes for 2 out of 2 years (2014 and 2015) reviewed. Findings included: Observation on 12/03/2015, at 9:40 a.m., showed the M280 Unico Microscope did not have a service sticker from a certified professional company. Review of the M280 Unico Microscope Manufacturer's instructions showed that the microscope should be professionally serviced once a year. During an interview with the Clinical Manager on at 10:00 a.m., the laboratory failed to provide evidence to demonstrate that the M280 Unico Microscope was professionally serviced annually.	L2909		

RICK SCOTT
GOVERNOR

ELIZABETH DUDEK
SECRETARY

, 2015

Administrator
Planned Parenthood of Southwest & Central Florida
8068 N 56th Street
Tampa, FL 33617

Dear Administrator:

This letter reports the findings of a relicensure survey that was conducted on , **2015** by representative(s) of this office.

Attached is the provider's copy of the State (3020) Form, which indicates the deficiencies that were identified on the day of the visit.

Please provide a plan of correction to this Field Office, in accordance with enclosed instructions, for the identified deficiencies **within ten calendar days of receipt of this faxed report**. You will not receive a copy of this report in the mail; you will only receive this faxed report. **All deficiencies shall be corrected no later than , 2016.**

The plan of correction must include the following:

1. Documentation showing what corrective action(s) have been taken for patients found to have been affected by the deficient practice;

2. How the laboratory has identified other patients having the potential to be affected by the same deficient practice and what corrective action(s) has been taken;

3. What measure has been put into place or what systemic changes you have made to ensure that the deficient practice does not recur, and

4. How the corrective action(s) are being monitored to ensure the deficient practice does not recur.

5. You must sign the bottom of page 1 of the statement of deficiencies; include your title and date.

The Quality Assurance Questionnaire has long been employed to obtain your feedback following survey activity. This form has been placed on the Agency's website at http://ahca.myflorida.com/Publications/Forms.shtml as a first step in providing a web-based interactive consumer satisfaction survey system. You may access the questionnaire through the link under Health Facilities and Providers on this page. Your feedback is encouraged and

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valued, as our goal is to ensure the professional and consistent application of the survey process.

Thank you for the assistance provided to the surveyor(s). Should you have any questions please call Jill Sutter, HFE Supervisor at (727) 552-2000.

Sincerely,

Patricia Reid Caufman
Field Office Manager

PRC/dw
Enclosure(s)

TBB2