STATE OF WASHINGTON
DEPARTMENT OF HEALTH
HEALTH SYSTEMS QUALITY ASSURANCE
Office of Laboratory Quality Assurance
16201 East Indiana Avenue
Suite 1500
Spokane Valley, WA 99216

60157121
~~MTS-60146547~~

November 4, 2015

Denise Bayuszik, MD
Planned Parenthood of Greater Washington and N Idaho
1117 Tieton Drive
Yakima WA 98902-3835

Dear Doctor Bayuszik:

We have reviewed the corrections for the deficiencies cited during the on-site survey of July 13-14, 2015. The corrections bring your medical test site into compliance with the requirements of Chapter 70.42 RCW and Chapter 246-338 WAC.

If you have any questions or comments, please contact me at (509) 995-4311.

Sincerely,

Lori Eschenbacher

Lori Eschenbacher, BSMT(ASCP) CLS(NCA)
Laboratory Surveyor and Consultant
Office of Laboratory Quality Assurance

cc: Alicia Trevino

Americans United for Life

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Planned Parenthood of Greater Washington and North Idaho

RH CONTROL & TEST LOG

Health Center: Walla Walla Date: 10 / 7 / 2015

Test Kit Room Temperature: 75° (Acceptable range is 41° – 99° F)

Control Fridge Temperature: 45° (Acceptable range is 2-8°C/35-46°F)

Rh-Eldon card lot#: 15181 Exp Date: 4 / 2017
Mo Yr

- If control sample is compromised, or if sample is more than 30-days old, do not use.
- For commercially prepared control samples, may use until expired, unless they get compromised.

Rh proficiency testing positive sample # or staff initials 2015IMMB #7

Control test result: +pos / -neg (Acceptable result is Positive)

Rh proficiency testing negative sample # or staff initials 2015IMMB #8

Control test result: +pos / -neg (Acceptable result is Negative)

Corrective Action if indicated:

Staff Signature and Title approving Rh Client Testing to start: Rhetta Hartwell

Americans United for Life

QA 05.007.05 (09/15)

DOS 10/7/15 Eldon Card Lot # 15181 Expiration Date 4/2017

Line through any unused rows.

Client ID Label	RH Factor Results +pos	RH Factor Results -neg	Rh-HR control (+pos/ -neg)	Patient Test corrective action if needed and Staff Signature & Title
CHART #: [redacted] DOB: [redacted]	+		−	Rhetta Hartwell

End of Day QA Satisfactory? (Yes / No (circle), if No, document corrective action on page-1.

QA Completed By:

Rhetta Hartwell, MAR — PRINTED NAME

Rhetta Hartwell — SIGNATURE

Medical Assistant Registered — TITLE

Page # 2 / 2

QA 05.007.05 (09/15)

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RH CONTROL & TEST LOG

Health Center: Yakima Date: 10 / 01 / 15

Test Kit Room Temperature: 70° (Acceptable range is 41° – 99° F)

Control Fridge Temperature: 41° (Acceptable range is 2-8°C/35-46°F)

Rh-Eldon card lot#: 14341 Exp Date: 08 / 16
Mo Yr

- **If control sample is compromised, or if sample is more than 30-days old, do not use.**
- **For commercially prepared control samples, may use until expired, unless they get compromised.**

Rh proficiency testing positive sample # or staff initials KB

Control test result: (+pos) / -neg (Acceptable result is Positive)

Rh proficiency testing negative sample # or staff initials RH

Control test result: +pos / (-neg) (Acceptable result is Negative)

Corrective Action if indicated:

Staff Signature and Title approving Rh Client Testing to start: K.B CTC

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QA 05.007.05 (09/15)

DOS 10.01.15 Eldon Card Lot # 14341 Expiration Date 08.16

Line through any unused rows.

Client ID Label	RH Factor Results		Rh-HR control	Patient Test corrective action if needed and Staff Signature & Title
	+pos	-neg	(+pos/ -neg)	
				none done today KB

End of Day QA Satisfactory? Yes / No (circle), if No, document corrective action on page 1.

QA Completed By:

Keri Brown
PRINTED NAME

SIGNATURE

CTC
TITLE

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Page # 1 / 1

QA 05.007.05 (09/15)

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RH CONTROL & TEST LOG

Health Center: Yakima Date: 10 / 06 / 15

Test Kit Room Temperature: 70° (Acceptable range is 41° – 99° F)

Control Fridge Temperature: 38° (Acceptable range is 2-8°C/35-46°F)

Rh-Eldon card lot#: 14341 Exp Date: 08 / 16
MO YR

- **If control sample is compromised, or if sample is more than 30-days old, do not use.**
- **For commercially prepared control samples, may use until expired, unless they get compromised.**

Rh proficiency testing positive sample # or staff initials KB

Control test result: (+pos) -neg (Acceptable result is Positive)

Rh proficiency testing negative sample # or staff initials RH

Control test result: +pos (-neg) (Acceptable result is Negative)

Corrective Action if indicated:

Staff Signature and Title approving Rh Client Testing to start: K. B GC

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QA 05.007.05 (09/15)

DOS 10·06·15	Eldon Card Lot # 14341	Expiration Date 08·16

Line through any unused rows.

Client ID Label	RH Factor Results +pos	RH Factor Results -neg	Rh-HR control (+pos/-neg)	Patient Test corrective action if needed and Staff Signature & Title
[redacted]	(+)		(−)	[signature] MAK
[redacted]	(+)		(−)	[signature] CSS
[redacted]	(+)		(−)	[signature]
3 total QA				

End of Day QA Satisfactory? (Yes) / No (circle), if No, document corrective action on page 1.

QA Completed By:

E. Andrews — PRINTED NAME

[signature] — SIGNATURE

RN — TITLE

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RH CONTROL & TEST LOG

Health Center: Yakima Date: 10/07/15

Test Kit Room Temperature: 70° (Acceptable range is 41° – 99° F)

Control Fridge Temperature: 42° (Acceptable range is 2-8°C/35-46°F)

Rh-Eldon card lot#: 14341 Exp Date: 08/16 (Mo / Yr)

- **If control sample is compromised, or if sample is more than 30-days old, do not use.**
- **For commercially prepared control samples, may use until expired, unless they get compromised.**

Rh proficiency testing positive sample # or staff initials KB

Control test result: +pos / -neg (Acceptable result is Positive)

Rh proficiency testing negative sample # or staff initials RH

Control test result: +pos / -neg (Acceptable result is Negative)

Corrective Action if indicated:

Staff Signature and Title approving Rh Client Testing to start: K.B. CTC

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QA 05.007.05 (09/15)

DOS	10·07·15	Eldon Card Lot #	14341	Expiration Date	08·16

Line through any unused rows.

Client ID Label	RH Factor Results		Rh-HR control	Patient Test corrective action if needed and Staff Signature & Title
	+pos	-neg	(+pos/ -neg)	
1 [redacted]	(+)		(−)	[signature] —MAAR
				1 done KVB

End of Day QA Satisfactory? Yes / No (circle), if No, document corrective action on page 1.

QA Completed By:

Keri Brown — PRINTED NAME

[signature] — SIGNATURE

CTC — TITLE

Page # 02 / 02

QA 05.007.05 (09/15)

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RH CONTROL & TEST LOG

Health Center: Yakima Date: 10 / [redacted] / 15

Test Kit Room Temperature: 70° (Acceptable range is 41° – 99° F)

Control Fridge Temperature: 38° (Acceptable range is 2-8°C/35-46°F)

Rh-Eldon card lot#: 14341 Exp Date: 08 / [redacted]
Mo Yr

- **If control sample is compromised, or if sample is more than 30-days old, do not use.**
- **For commercially prepared control samples, may use until expired, unless they get compromised.**

Rh proficiency testing positive sample # or staff initials KB

Control test result: (+pos) / -neg (Acceptable result is Positive) [redacted]

Rh proficiency testing negative sample # or staff initials KH

Control test result: +pos / (-neg) (Acceptable result is Negative) [redacted]

Corrective Action if indicated:

[redacted]

Staff Signature and Title approving Rh Client Testing to start: KB CTC

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QA 05.007.05 (09/15)

DOS 10-14-15 | Eldon Card Lot # 14341 | Expiration Date 08-16

Line through any unused rows.

Client ID Label	RH Factor Results +pos	RH Factor Results -neg	Rh-HR control (+pos/ -neg)	Patient Test corrective action if needed and Staff Signature & Title
[redacted]	+		−	
[redacted]	error +	−	−	
[redacted]	+		−	CBS
[redacted]	+		−	KMAR
[redacted]	+		−	
[redacted]	+		−	KMAR
				6 total

End of Day QA Satisfactory? Yes / No (circle), if No, document corrective action on page 1.

QA Completed By:

Keri Brown — PRINTED NAME

SIGNATURE

CTC — TITLE

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Page # 02 / 02

QA 05.007.05 (09/15)

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RH CONTROL & TEST LOG

Health Center: Yakima Date: 10 / 13 / 15

Test Kit Room Temperature: 70° (Acceptable range is 41° – 99° F)

Control Fridge Temperature: 40° (Acceptable range is 2-8°C/35-46°F)

Rh-Eldon card lot#: 14341 Exp Date: 08 / 16
Mo Yr

- **If control sample is compromised, or if sample is more than 30-days old, do not use.**
- **For commercially prepared control samples, may use until expired, unless they get compromised.**

Rh proficiency testing positive sample # or staff initials KB

Control test result: (+pos) / -neg (Acceptable result is Positive)

Rh proficiency testing negative sample # or staff initials RH

Control test result: +pos / (-neg) (Acceptable result is Negative)

Corrective Action if indicated:

Staff Signature and Title approving Rh Client Testing to start: K.B CTC

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QA 05.007.05 (09/15)

DOS 10.13.15 Eldon Card Lot # 14341 Expiration Date 08.16

Line through any unused rows.

Client ID Label	RH Factor Results +pos	RH Factor Results -neg	Rh-HR control (+pos/ -neg)	Patient Test corrective action if needed and Staff Signature & Title
✓ [redacted]	+		−	CSS
✓ [redacted]	+		−	MAR
✓ [redacted]	+		−	MAR
✓ [redacted]	+		−	CSS
✓ [redacted]	+		−	CSS

End of Day QA Satisfactory? Yes / No (circle), if No, document corrective action on page 1

QA Completed By:

Alicia Trevino — PRINTED NAME

SIGNATURE

CSS — TITLE

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Page # 02 / 08

QA 05.007.05 (09/15)

PPGWNI's policy is to be in compliance with quality assurance efforts in the practice of providing laboratory services to our clients.

There are several laboratory control logs that direct personnel in day-to-day operations and control processes toward this goal. This is a guide on the expectations for documentation on these logs.

Best Practices for Documentation on Laboratory Control Logs

- Use blue or black ink only so that photocopies and scans for archiving purposes are legible; do not use colored ink pens or pencil.
- Write legibly and when an error needs corrected, line through once and write in the correction with your initials and date.
- Line through any unused lines to close out a service day or month.
- Do not use white out, or markers to black out sections of documentation.
- Document any steps taken for corrective action when results or monitoring is not as expected per the laboratory procedures.
- Stamp or write on the log sheet once it is closed out and has been scanned to the QA department for archive; verify your scan quality before submitting.
- When using initials, be sure to indicate your initials and full printed name and title in the footer of the log.
- Indicate page numbers when a service day continues onto multiple log sheets.
- Be sure to complete all fields on the log sheet, write N/A or line through areas that do not apply.

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INTRODUCTION

Introduction

PPGWNI will operate its clinic laboratory services in accordance with the Washington State Medical Test Site Rule, WAC 246-3338. PPGWNI holds a current medical test site license classified as category low volume issued by Washington State.

Personnel

The Medical Director is the Laboratory Director for PPGWNI and in partnership with the Lead Clinician is responsible for:

- Overall technical supervision and management of the test sites
- Assuring technical personnel are competent to perform tests
- Establishment of policies for performing, recording and reporting tests

The testing personnel, including clinicians, nurses and medical assistants, are responsible for specimen collection, specimen processing, quality control, test performance, interpreting of results, accurate documentation and reporting any adverse testing events. Documentation of training and education of clinic staff performing lab tests/ procedures will be maintained in personnel files.

Laboratory Test Categories

There are four categories of laboratory tests outlined by the federal Clinical Laboratory Improvement Act, CLIA. These are Waived, Provider Performed Microscopic Procedures (PPMP), Moderate Complexity and High Complexity tests. The tests are placed in each category based upon their performance characteristics and the risk of harm to a client if there is an erroneous result. PPGWNI's medical test site license category low volume allows our staff to perform waived, PPMP and moderate complexity testing.

Laboratory Testing Policies

- All laboratory testing at PPGWNI is ordered directly by a clinician, or per written protocol. All staff who perform laboratory tests **must** meet applicable certification or licensing requirements (Planned Parenthood, State, and Federal).

- It is the responsibility of the laboratory testing personnel to read and follow the procedures outlined in this manual and in the testing product manufacturer's information. *Only appropriately trained clinical staff can perform laboratory procedures after completing initial skill training and competency check-list.*

    - PPGWNI utilizes external laboratories for tests not processed internally including: cytology, histology, STI, and others as ordered. Refer to Tab 02b - CDD Lab Test Collect-N'-Ship Spreadsheet for proper selection of vials, processing, and shipping requirements.

Client Test Management

It is the policy of PPGWNI to assure optimum client specimen integrity and identification. From the moment of specimen collection, labeling, storage, and testing or shipment to a reference laboratory, laboratory procedures **must** be closely followed to assure positive client identification, suitability of the specimen for the testing required and acceptable test quality control.

- Log sheets will be used to document all quality control results, maintenance procedures, instrument checks, comments, and any task performed in the laboratory as required.

- Clients will be prepared, samples collected, labeled, preserved and transported according to the written procedures outlined below and/or by the manufacture.
- Samples will be rejected and a repeat requested if, according to the procedure, it is not acceptable. The condition of the sample **must** be documented on the lab report if significant.
- Criteria for specimen rejection will include:
  1. Unlabeled samples. All specimens must have a minimum of 2 client identifiers.
  2. Hemolyzed blood samples
  3. Samples exposed to extremes of heat or cold.
  4. Any deviation from the written procedure.
- All lab tests performed at PPGWNI will be completed as soon as possible and ideally while the client is in the clinic.
- Documentation of quality control results is required and must be easily traceable to the specific test/s and date/s for each client test performed.
- Test orders and results will be documented directly into the client's chart.
- Corrections of lab errors will be made according to these guidelines. If a test result is corrected by an outside laboratory, the clinician will be notified immediately and the client's chart will be corrected. The client will be notified in accordance with PPGWNI follow-up procedures.

Quality Control Procedures

Quality control procedures will be performed and documented for each laboratory test as indicated in the specific written test procedure. Quality control test results **must** be evaluated to ensure they are within acceptable ranges, or produce expected results, before client testing can be performed. Quality control procedures also include the checking and documentation of reagent lot numbers and expiration dates on the associated log sheet. See specific laboratory procedures in this chapter for additional procedure details. Procedures are reviewed annually by the clinical quality department.

Corrective Action – Quality Control Troubleshooting

For corrective action in the event control/reagent checks are incorrect, the following steps will be taken:

1. Re-test the quality control test. *If it is still incorrect:*
2. Do not begin client testing.
3. Notify the Health Center Management immediately.
4. Troubleshoot the testing process:
   a) Was the test performed correctly?
   b) Are the kit reagents expired?
   c) Was the result read correctly?
   d) Is quality control material expired?
   e) Are reagents and testing environment temperatures within range; such as fridge and view box?
   f) By visual inspection, do reagents, controls, etc. appear contaminated?

5. If possible, correct the problem per #4 above and re-run and document test, including any corrective action taken. (If needed, open a new package of test materials and re-run test).
6. If satisfactory results are obtained, begin client testing.
7. If the problem is not corrected, suspend client testing until the problem is resolved and contact the manufacturer for assistance as indicated.
8. Notify the clinical quality department and submit an incident report.
9. If a defective lot is suspected, pull the lot and notify the Finance Manager for non-mechanical failure, and Facility Manager for mechanical failure.

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Provider Performed Microscopic Procedures (PPMP)

The following tests are considered PPMP category performed in conjunction with client visits. These tests are non-regulated, non-waived analytes and require twice yearly assessment of the laboratory examiner often called proficiency testing or biannual verification programs. Proficiency testing is completed through services provided by API. Testing and record retention is conducted by the clinical quality department. The following provider performed microscopic procedures are conducted at PPGWNI:

Test Name	Manufacturer	Use	Quality Control
Wet mounts, including preparations of vaginal, urethral or cervical fluid specimens in a suspension of sterile saline.	None	For the diagnosis of vaginal infections detected by the presence of organisms such as yeast or bacterial species, histological characteristic epithelial cell types (Clue cells) and specific immune cell components such as leukocytes under high-power microscopic exam.	Biannual proficiency testing.
Potassium hydroxide (KOH) preparations.	None	For the diagnosis of vaginal infections detected by a positive whiff test when KOH applied to specimen, presence of organisms and or cellular components.	Biannual proficiency testing.
Post Vasectomy Semen Analysis-qualitative	None	For the qualitative inspection of post-vasectomy semen specimens for the presence or absence of sperm and motility. A simple slide count per high powered field and a motility assessment of a semen specimen collected without condom or lubrication.	Biannual proficiency testing.
Saline, TCA and KOH will be checked daily (visually) for contamination. Note in cooler weather, KOH crystals may form in the KOH solution which is a natural occurrence. Otherwise, the TCA and KOH solutions expire per the manufacturer. Saline solutions should be clear; if precipitation is present dispose of solution. Saline or water dropper bottles must be changed at least monthly. Person Responsible: Clinical Back Office Manager.			

Rh Testing

Rh testing is necessary to determine if the woman is Rh positive or Rh negative. An Rh negative woman who has a medical, surgical or spontaneous abortion and had an Rh positive embryo/fetus has a very small chance of being exposed to embryonic blood. This occurs as an embryo/fetus –maternal hemorrhage during the procedure. About 17% of women become sensitized when as little as 0.1 cc of blood (or early blood protein) enters maternal circulation. If the exposure to blood is large enough in quantity, an Rh negative woman could develop antibodies to blood from the Rh positive embryo/fetus. Her immune system recognizes this exposure as being foreign to her body and responds by producing antibodies against it. She thus becomes sensitized to the Rh antigen. Once sensitized her immune system will respond to future Rh positive blood exposure by releasing antibodies that can cross the placenta and attach to the Rh antigen sites found on the blood cells of an Rh positive fetus. This may greatly reduce the survival of the fetal red blood cells and cause mild or even fatal harm to the fetus. To prevent an Rh negative woman from becoming sensitized we administer MicroRhoGam (or Rhogam when 13+ weeks). This is a special immune globulin that temporarily suppresses the Rh immune response so she does not become sensitized and produce antibodies that might harm to a future pregnancy."

Who Needs Rh Testing?

- Clients planning abortions at PPGWNI **must** have Rh testing done as a part of the abortion procedure.
- Clients with a positive pregnancy test being evaluated for complication, or miscarriage management.
- On the day of the abortion Rh testing will be performed. Except if previously done during a prior visit, or the client supplies sufficient documentation of the testing performed elsewhere.

Personnel and Training:

- Rh testing is considered a moderate complexity test. This test will be performed by staff that have been trained and checked off for competency by the trainer designee. Completion of Rh testing training will be documented in the employee's personnel file. Training will consist of the review of the procedure and performance of a minimum of ten tests directly with the trainer before being awarded the competency certificate.

- To maintain their certificate, each staff member will be required to participate in the American Proficiency Institute's Rh testing program. This program consists of triennial testing periods where a staff member will perform Rh tests on samples sent from American Proficiency Institute, record the results on a log sheet also provided by API and submit those back to API for review. One staff member will be selected by rotation for proficiency testing on a cyclic basis. All other staff who perform Rh testing and who are not up for proficiency review will also participate in the API sample testing triennially to maintain competency standards.

The clinical quality department will be responsible for:

- Ensuring that all staff receiving their competency and proficiency testing at their designated intervals.
- Ensuring that designated staff submit the proficiency testing answers to API on time.
- Retrieval and review of the proficiency testing results.
- External controls are being run appropriately and client test results are recorded accurately.
- Alert Medical Director of any corrective actions.

PPGWNI's American Proficiency Institute account is set-up for API to:

- Submit the results of our Rh proficiency testing to the Department of Health for each site that performs the test.

- Submit an announcement that the results are ready for review online to designated employees.

- Prompt action will be taken to correct any found deficiencies. Each staff members continued approval to perform Rh testing will be dependent upon satisfactory completion of the proficiency testing.

Materials and Procedure:

- Lancet
- Isopropyl alcohol pad
- Band aids
- Clay sealant
- Gloves
- Sharps container
- EldonCard® from Doctor's Kit DKS RhD-25

Follow all manufacture instructions included in the kit for processing a capillary blood sample.

- This is a single-use test kit.
- Perform test at room temperature.
- Avoid any infection.
- Wash your hands before and after the blood testing.
- Do not use any of the accessories coming into contact with the blood for more than one person.

Documentation:

1. Every client who has received an Rh test at PPGWNI **must** have the result of the Rh factor, positive or negative. See Results below.

   If a positive reaction is observed in the Control field, the test result is invalid and the examination has to be repeated, either with washed blood cells or by diluting the blood with isotonic saline, until agglutination in the control field fails to appear.

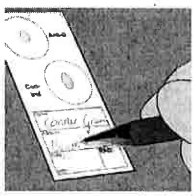
2. If a client can produce sufficient proof of prior Rh testing, PPGWNI testing may be waived and this must be documented in the medical record.

3. If an error is made in a client's medical record, such as documentation of the wrong Rh test result, the same procedure for correcting all medical record mistakes will be used.

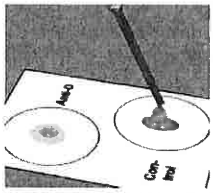
   - **If the client is still in the clinic, immediate action must be taken to inform the clinician and client of the error.**
   - **If the client has already left the clinic, the clinician must be informed at the soonest reasonable opportunity and a good-faith effort to notify the client must be made.**
   - **For an Rh negative client who incorrectly did not receive a Rhogam injection, a good-faith effort will be defined as the same requirement to confirm care for a client with an acute, emergency referral. The client will be placed in Health watcher as an "emergent" follow up. (Notification attempts are preloaded in to the EMR).** Submit an occurrence report.

Below referenced from manufacture instruction insert:

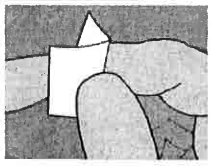
Kit with 25 ELDONCARD RhD for 75 Determinations of Rhesus Factor (Slide technique)
Instructions for Use No. 473 (rev. 2007-07-11)
C: Instruction for Use of Capillary Blood (Procedure 3): (Also shown with one third of a card)



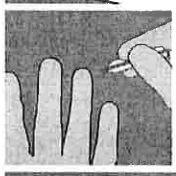
1. Fill in the data of the client being tested.



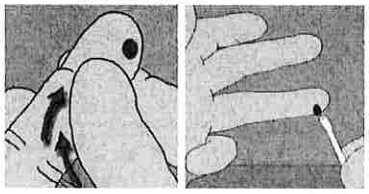
2: Apply one drop of water onto each of the coloured reagent spots, using the plastic pipette.



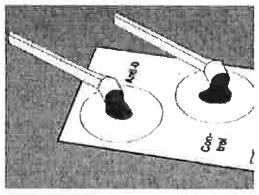
3: Disinfect the finger at the puncture site and let the finger air-dry.



4: Puncture the skin by pressing the lancet firmly against the side of the fingertip.



5: Gently massage the finger close to the puncture site to obtain a drop of blood. Collect the drop onto an EldonStick which is approached from beneath. Place the stick onto the AntiD field. The blood shall touch the water applied in step 2.



6: Repeat the procedure in step 5 using another EldonStick. Keep each stick inside its own field. Use a new stick for each field.

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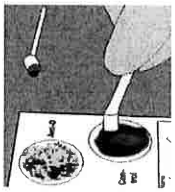
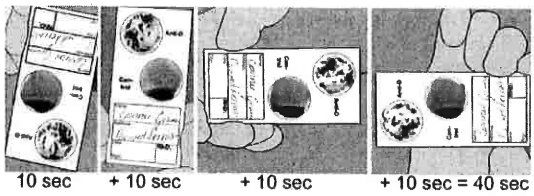


7. Stir the blood in the Anti-D field with an Eldon Stick until the reagent is completely dissolved (approx. 10 sec). Then spread the blood to cover the entire field.
Repeat the procedure in the Control field using another Eldon Stick.

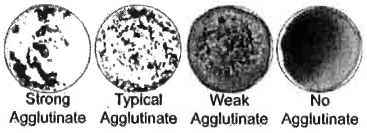


8: To develop a possible agglutinate, the card **must** be tilted for at least 40 seconds.
Tilt the EldonCard to an almost upright position and wait 10 seconds. A wave of blood will move the red cells slowly to the bottom of the fields.
Tilt to the opposite vertical position and wait another 10 seconds while the blood flows down the fields.
Tilt twice more on the remaining edges for 10 + 10 seconds.
The results can now be read and recorded. See Results.

How to read the results
The presence or absence of an agglutinate in the Anti-D field indicates the presence or absence of the Rhesus factor.
Agglutinates may look different from test person to test person, see the examples below.
Any test producing a weak agglutinate **must** be repeated.

If a positive reaction is observed in the Control field, the test result is invalid and the examination has to be repeated, either with washed blood cells or by diluting the blood with isotonic saline, until agglutination in the control field fail to appear.

Examples of agglutinates



Quality Control:
1. On a day-of-use basis the testing kit supply is checked with external positive and negative controls before any client samples are tested for the day, or upon abnormal testing events, and results are recorded.
2. Test kits and reagents are properly labeled, stored at the proper temperature, and used within expiration date.
3. Foil envelope **must** be marked with date opened and unused test cards **must** be discarded after 6-months or by expiration date, or whichever comes first.
4. Control blood samples **must** be stored refrigerated between 2-8 degrees Celsius. They may be at room temperature while in use. They are usable until hemolyzation (clotting) occurs or manufacture expiration, whichever occurs first. Acceptable known positive and negative Rh factor control samples include:
   - samples that are received from the American Proficiency Institute's Rh proficiency testing program

- external lab verified staff/volunteer donated blood samples-consent forms from volunteer/employee are on file. External lab validation results are located in the lab log for each volunteer/employee.
- purchased manufactured control samples

5. Testing of controls will be performed in the same manner as a client's blood sample, which is described above.
6. Control test is acceptable if:
   - Rh positive control blood tests as positive.
   - Rh negative control blood tests as Rh negative.

Post Vasectomy Semen Analysis

Personnel

All Clinicians at PPGWNI are trained to perform post vasectomy semen analysis-qualitative. These can be scheduled anytime a clinician is on-site.

Quality Assurance

Participation of biannual proficiency testing through API is required for each provider performing this microscopic test.

Specimen Requirements

1. Client should be instructed to return to the health center for this testing and provided instruction for submitting a sample.
2. As part of Vasectomy post-op care, client is given: specimen supplies and instructions.
3. Semen samples should be collected after 2-days of abstinence and before more than 7-days of abstinence.
4. Give sterile specimen cup and instruct to collect entire ejaculate by masturbation into the container. Specimen must be labeled with:
   - 2 client identifiers
   - Source of specimen: semen
   - Time of collection
5. Instruct the client the specimen must be kept warm (room temperature) and it needs to be brought to the clinic within 30-60 minutes.
6. **The specimen is no longer satisfactory for evaluation after 4-hours.**

Supplies and Equipment

- Sterile specimen collection cups and client ID labels
- Glass microscope slides, 3" x 1"
- 22 x 22 mm cover slips
- Small disposable pipettes

Procedure

- Mix sample well in cup-ensure liquefaction.
- Pipette a drop onto glass slide and cover

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
HEALTH SYSTEMS QUALITY ASSURANCE
Office of Laboratory Quality Assurance
16201 East Indiana Avenue
Suite 1500
Spokane Valley, WA 99216

August 5, 2015

MTS-60157121

Denise Bayuszik, MD
Planned Parenthood of Greater Washington and North Idaho
1117 Tieton Drive
Yakima, WA 98902-3835

Dear Doctor Bayuszik:

We have reviewed and approved your written plan of correction for the deficiencies cited during the on-site survey of your medical test site on July 13-14, 2015. Corrections of the deficiencies cited must be completed by **October 5, 2015**.

The department will contact you for verification that these corrections have been completed. Failure to comply within this time period could result in the department initiating disciplinary action, as described under Chapter 70.42 RCW and WAC 246-338-100.

If you have any questions or comments, please contact me at (509) 995-4311.

Sincerely,

Lori Eschenbacher

Lori Eschenbacher, BSMT(ASCP) CLS(NCA)
Laboratory Surveyor and Consultant
Office of Laboratory Quality Assurance

cc: Alicia Trevino

Americans United for Life

WASHINGTON STATE DEPARTMENT OF HEALTH
Office of Laboratory Quality Assurance
16201 East Indiana Avenue, Suite #1500
Spokane Valley, WA 99216

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION

MEDICAL TEST SITE: Planned Parenthood of Greater WA and N Idaho **MTS-60157121**
ADDRESS: 1117 Tieton Drive **DATE OF SURVEY:** July 13-14, 2015
CITY/ZIP: Yakima, WA 98902-3835
MEDICAL TEST SITE DIRECTOR: Denise Bayuszik, MD
LICENSING OR CERTIFICATION REQUIREMENTS USED: Chapter 70.42 RCW, WAC 246-338

NOTE: This document contains a listing of the deficiencies cited as requiring correction. The Statement of Deficiencies is based on the surveyor's professional knowledge and interpretation of the requirements for medical test site licensure. In the column PLAN OF CORRECTION, the statements should reflect the facility's plan of correction and anticipated time of correction.

WAC: 246-338-070(2)(a)	SECTION: RECORDS	PLAN OF CORRECTION
Based upon record review and staff interview, the medical test site had no patient results recorded on the log for Rh testing performed on 12/31/14 at the Walla Walla site. External quality control was performed, but no patient results were logged on the form and three patients had been tested that day.		**HOW** the deficiency will be corrected: "End of day QA" The deficiency will be corrected by QA at the end of each testing day and signed off. The QA person will look for: -Correct site and date of testing; -All clients tested are logged with results, lot code/exp date, and date of test; -Both positive and negative external controls documented; -Temperatures documented of kit storage, testing are and control samples. If out of range, responded to. QA staffer will initial the log(s) indicating their review is complete and satisfactory. Unsatisfactory findings are to be reported to the service coordinator. **WHO** is responsible for making the corrections: Service Coordinator of the day. **WHAT** will be done to prevent reoccurrence and monitor for compliance: Monthly monitoring of the deficiency correction plan will be done by the Cient Services Specialist, who will also submit control and patient test logs to Lori monthly as requested. **WHEN** the corrections will be completed: We are starting the "end of day QA" process in the clinics 8/3/15, and logs scanned at end of month for monitoring and continue monthly.

Surveyor Signature/Date:
Lori Eschenbacher 8/5/15

The completion and signing of this form constitutes acceptance of the plan of correction unless the Department notifies the facility to the contrary within fifteen days of receipt.

Director Signature/Date:
Denise Bayuszik MD 8/4/2015

I certify that I understand the deficiency(ies) and agree to correct them as outlined by the dates indicated.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION, cont.

MEDICAL TEST SITE: Planned Parenthood of Greater WA and N Idaho **DATE OF SURVEY:** July 13-14, 2015

WAC: 246-338-080(2)(f)	SECTION: QUALITY ASSURANCE	PLAN OF CORRECTION
Based upon record review and staff interview, the medical test site had no policy for how to issue corrected reports, including the following: 1) how to make changes in the EMR and report those changes to providers, and 2) how to make changes to patient logs, temperature charts and other paperwork.		**HOW** the deficiency will be corrected: The Director of Clinician Services will write into our internal lab procedures, staff instructions for how to make changes in EMR, communicate the correction to the provider as necessary, and how to amend lab logs. **WHO** is responsible for making the corrections: Director of Clinician Services **WHAT** will be done to prevent reoccurrence and monitor for compliance: The Client Services Specialist will be communicating with the service coordinator if corrections are needed and then monitoring to ensure documentation was done per policy. **WHEN** the corrections will be completed: To complete document revision and staff training, this will be complete by 10/1/15.

WAC: 246-338-080(3)	SECTION: QUALITY ASSURANCE	PLAN OF CORRECTION
Based upon record review and staff interview, the site had no documentation of corrective action taken for refrigerator temperatures below the acceptable range of 35 – 46 F. On 6/29/15 the refrigerator temperature was recorded as 30 degrees F at the Walla Walla location, and in Yakima the refrigerator temperature was 50 degrees on 6/9/15.		**HOW** the deficiency will be corrected: Acutely, staff have been verbally trained to use an attached sheet of paper or the back of the log to capture the steps they are taking to report if the temperature goes out of range. We are writing the policy of expectation of what to do with unexpected results, how to document this, and will provide staff re-training per plan above. Managers will also be included in the procedure for corrective action steps and participate in the training. The log sheet will be revised and combined to include control testing event, temperatures of storage, testing area and controls, corrective action promptsand each client test event for the date of service. **WHO** is responsible for making the corrections: Director of Clinician Services and Lab Director **WHAT** will be done to prevent reoccurrence and monitor for compliance: Monthly monitoring of the deficiency correction plan will be done by the Cient Services Specialist. **WHEN** the corrections will be completed: August end of month monitoring will begin. Updated combined log mid-late August publication date.

Surveyor initials LE

Director initials ND

WASHINGTON STATE DEPARTMENT OF HEALTH
OFFICE OF LABORATORY QUALITY ASSURANCE

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION, cont.

MEDICAL TEST SITE: Planned Parenthood of Greater WA and N Idaho **DATE OF SURVEY:** July 13-14, 2015

WAC:	SECTION:	PLAN OF CORRECTION
246-338-090(2)(a)	QUALITY CONTROL	

Based upon record review and staff interview, the medical test site had no documentation of the room temperature where testing takes place and where opened kits are stored since 7/2014.

Additionally, the refrigerator temperature was not recorded on 6/2/15 at the Yakima site, but patient testing had been performed.

HOW the deficiency will be corrected:
"End of day QA"
The deficiency will be corrected by QA at the end of each testing day and signed off. The QA person will look for:
-Correct site and date of testing;
-All clients tested are logged with results, lot code/exp date, and date of test;
-Both positive and negative external controls documented;
-Temperatures documented of kit storage, testing are and control samples. If out of range, responded to.
QA staffer will initial the log(s) indicating their review is complete and satisfactory. Unsatisfactory findings are to be reported to the service coordinator.

WHO is responsible for making the corrections:
Service Coordinator of the day

WHAT will be done to prevent reoccurrence and monitor for compliance:
Monthly monitoring of the deficiency correction plan will be done by the Cient Services Specialist, who will also submit control and patient test logs to Lori monthly as requested.

WHEN the corrections will be completed:
We are starting the "end of day QA" process in the clinics 8/3/15, and logs scanned at end of month for monitoring and continue monthly.

Americans United for Life

Surveyor Initials: tw

Director Initials: [illegible]

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
HEALTH SYSTEMS QUALITY ASSURANCE
Office of Laboratory Quality Assurance
16201 East Indiana Avenue
Suite 1500
Spokane Valley, WA 99216

July 21, 2015

MTS-60146547

Denise Bayuszik, MD
Planned Parenthood of Greater Washington and N Idaho
1117 Tieton Drive
Yakima WA 98902-3835

Dear Doctor Bayuszik:

Enclosed is a list of the deficiencies found at your medical test site during the on-site surveys on July 13-14, 2015. These deficiencies and other points were discussed with your staff at the time of the survey. The deficiencies have been cited as concisely as possible, since this statement becomes part of the public record.

The right side of the form is for your statement, item by item, of the Plan of Correction for each deficiency. Each correction statement must include the following:

HOW the deficiency will be corrected
WHO is responsible for making the corrections
WHAT will be done to prevent reoccurrence and monitor for compliance and
WHEN the corrections will be completed.

Please complete the plan of correction, sign the form (**Director's** signature), retain a copy for your records, and return the original to us by **August 4, 2015** at the following address:

PO Box 142
Nine Mile Falls, WA 99026

Correction of the deficiencies cited must be completed within a specified time, not to exceed sixty days after department approval of your written plan of correction. The department will contact you for verification that these corrections have been completed. Failure to comply within this time period could result in the department initiating disciplinary action, as described under Chapter 70.42 RCW and WAC 246-338-100.

During your survey I made the following observations and recommendations, which I will review at your next regular survey:

- We discussed how to make proper changes to logs and other paperwork, which should be included in your new policy for how to make corrections to your results or logs.
- We also discussed how to make it clear to testing personnel when the proficiency testing samples have expired when used for competency, control verification, etc.

If you disagree with the surveyor's judgments or observations, you may submit your objections, in writing, with your plan of correction.

Feel free to contact me at (509) 995-4311 for any questions or comments.

Sincerely,

Lori Eschenbacher

Lori Eschenbacher, BSMT(ASCP) CLS(NCA)
Laboratory Surveyor and Consultant
Office of Laboratory Quality Assurance

Enclosure

cc: Alicia Trevino

Americans United for Life

Credential View Screen [update]

Planned Parenthood of Greater Washington and North Idaho
Address:
○ Public ◉ Mail

[change mail address]
Planned Parenthood of Greater Washington and North Idaho
1117 Tieton Dr
Yakima, WA 98902-3835

ID	851898
Warnings	
SSN/FEIN	
Federal ID	916071384
Secretary Of StateNumber	397020704
CLIA	50D0697375
Contact Standing	In-Business
Contact Type	NON PROFIT CORPORATION
Public File	YES
Mailing List	
US Citizen	
Email:	anna.franks@ppgwhi.org

Contact
Audit
Enforceme
Cont. Edu
Documents
Owners
Owned By/
Exams
Experience
Notes
Schools
Librarian
Application
Other State
Online Info

Comments:

Medical Test Site Categorized License [update] [form letter]

Credential #	MTSC.FS.60157121
Application Date	05/04/2010
Effective Date	07/01/2015
Expiration Date	06/30/2017
First Issuance Date	05/11/2010
Last Date Of Contact	05/10/2010
Next Examinations Date	07/31/2015

Credential Status	ACTIVE (04/22/2015)
Status Reason	ACTIVE
Amount Due	$0.00
Date Last Activity	4/29/2015 2:19:43 PM
Last Updated by	Miller, Kathi D
Certificate Sent Date	04/22/2015

Audit
Documents
Verification
Workflow
Key Mgmt
Fees
Notes
Print Docs
Comp. Audit
Renewal
Medical Testir
License Statu

Comments:
- **User Defined License Data**
- **Workflow**

User Definable License Data [update]

Field	Value
Medical Test Site Type	Clinic
Multiple Sites	Yes
Lab Director	Denise Bayuszik MD
Lab Director's Email	denise.bayuszik@ppgwni.org
Lab Contact	~~Erica Garza ARNP~~ Alicia Trevino
Lab Contact Email	erica.garza@ppgwni.org
Lab Phone Number	866-904-7721
Lab Fax Number	509-576-8658

Field	Value
Medical Test Site Region	Region 4
MTS Category	_Low Volume
MTS Lab Testing Personnel 1	RN
MTS Lab Testing Personnel Quantity 1	~~1~~ 3
MTS Lab Testing Personnel 2	CMA
MTS Lab Testing Personnel Quantity 2	~~1~~ 2
MTS Lab Testing Personnel 3	On Job Training
MTS Lab Testing Personnel Quantity 3	~~8~~ 7

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Medical Testing - MTSC.FS.60157121

- SubSpecialty
- Tests
- Subscriber #

SubSpecialty [add] [show all]

Specialty	SubSpecialty	Volume	Effective Date	Expiration Date	Status	User	Date
500 Immunohematology	510 ABO & Rh Typing	1255	05/10/2010		Active	Eschenbacher, Lori A	8/2/2013 9:38:05 AM
	Total Volume	1255					

Note : Total Volume does not include inactive SubSpecialties and SubSpecialties not used to calculate volume for fees (highlighed in red).

Tests [add] [show all]

Specialty	SubSpecialty	Test	Status	Add Event	Recent Events	Event History	User	Date
500 Immunohematology	510 ABO & Rh Typing	87500 D(RH)Typing	Active	[add event]	133, 141, 142, 143	[history]	Terry, Vicky	5/10/2010 2:37:22 PM

Subscriber # [add]

Provider Name	Subscriber #	User	Date
American Proficiency Institute	03-57-96	Terry, Vicky	5/10/2010 2:37:38 PM
American Proficiency Institute	04-23-03	Terry, Vicky	5/10/2010 2:37:50 PM
American Proficiency Institute	05-33-38	Terry, Vicky	5/10/2010 2:38:00 PM
American Proficiency Institute	05-33-40	Terry, Vicky	5/10/2010 2:38:07 PM
American Proficiency Institute	03-57-96	Kargacin, Leonard	11/9/2010 6:00:04 AM
American Proficiency Institute	04-23-03	Kargacin, Leonard	11/9/2010 6:00:04 AM
American Proficiency Institute	05-33-40	Kargacin, Leonard	11/9/2010 6:00:04 AM
American Proficiency Institute	05-10-84	Kargacin, Leonard	5/6/2011 6:27:35 AM

Close

Americans United for Life

Credential View Screen [update]

Planned Parenthood of Greater Washington and North Idaho
Address:

○ Public ◉ Mail

[change mail address]
Planned Parenthood of Greater Washington and North Idaho
1117 Tieton Dr
Yakima, WA 98902-3835

ID	851898
Warnings	
SSN/FEIN	
Federal ID	916071384
Secretary Of StateNumber	397020704
CLIA	50D0697375
Contact Standing	In-Business
Contact Type	NON PROFIT CORPORATION
Public File	YES
Mailing List	
US Citizen	
Email:	anna.franks@ppgwhi.org

Contact
Audit
Enforceme
Cont. Edu
Documents
Owners
Owned By/
Exams
Experience
Notes
Schools
Librarian
Application
Other State
Online Info

Comments:

Medical Test Site Categorized License [update] [form letter]

Credential #	**MTSC.FS.60157121**
Application Date	05/04/2010
Effective Date	**07/01/2015**
Expiration Date	**06/30/2017**
First Issuance Date	05/11/2010
Last Date Of Contact	05/10/2010
Next Examinations Date	07/31/2015

Credential Status	ACTIVE (04/22/2015)
Status Reason	ACTIVE
Amount Due	**$0.00**
Date Last Activity	4/29/2015 2:19:43 PM
Last Updated by	Miller, Kathi D
Certificate Sent Date	04/22/2015

Audit
Documents
Verification
Workflow
Key Mgmt
Fees
Notes
Print Docs
Comp. Audit
Renewal
Medical Testir
License Statu

Comments:

- **User Defined License Data**
- **Workflow**

User Definable License Data

[update]

Field	Value
Medical Test Site Type	Clinic
Multiple Sites	Yes
Lab Director	Denise Bayuszik MD
Lab Director's Email	denise.bayuszik@ppgwni.org
Lab Contact	~~Erica Garza ARNP~~
Lab Contact Email	erica.garza@ppgwni.org
Lab Phone Number	866-904-7721
Lab Fax Number	509-576-8658

Field	Value
Medical Test Site Region	Region 4
MTS Category	_Low Volume
MTS Lab Testing Personnel 1	RN
MTS Lab Testing Personnel Quantity 1	1
MTS Lab Testing Personnel 2	CMA
MTS Lab Testing Personnel Quantity 2	1
MTS Lab Testing Personnel 3	On Job Training
MTS Lab Testing Personnel Quantity 3	5

Americans United for Life

Medical Testing - MTSC.FS.60157121

- SubSpecialty
- Tests
- Subscriber #

SubSpecialty [add] [show all]

Specialty	SubSpecialty	Volume	Effective Date	Expiration Date	Status	User	Date
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	Total Volume	1255					

Note : Total Volume does not include inactive SubSpecialties and SubSpecialties not used to calculate volume for fees (highlighed in red).

Tests [add] [show all]

Specialty	SubSpecialty	Test	Status	Add Event	Recent Events	Event History	User	Date
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Subscriber # [add]

Provider Name	Subscriber #	User	Date
American Proficiency Institute	03-57-96	Terry, Vicky	5/10/2010 2:37:38 PM
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American Proficiency Institute	05-33-40	Terry, Vicky	5/10/2010 2:38:07 PM
American Proficiency Institute	03-57-96	Kargacin, Leonard	11/9/2010 6:00:04 AM
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American Proficiency Institute	05-33-40	Kargacin, Leonard	11/9/2010 6:00:04 AM
American Proficiency Institute	05-10-84	Kargacin, Leonard	5/6/2011 6:27:35 AM

Close

Americans United for Life

Inspection Survey_x2015-1043.pdf redacted on: 3/12/2020 15:41

Redaction Summary (0 redactions)

0 Privilege / Exemption reason used:

Redacted pages: