

STATE OF WASHINGTON DEPARTMENT OF HEALTH

Office of Laboratory Quality Assurance Health Systems Quality Assurance 1610 NE 150th Street Shoreline, Washington 98155-9701

January 16, 2009

Michael Romo, MS, MT (ASCP) Planned Parenthood of Western Washington – Central Region 4500 9th Avenue NE, Suite 324 Seattle, Washington 98105

MTS-0038

Dear Mr. Romo:

I conducted an on-site survey of your Bremerton facility on January 15, 2009 and your West Seattle facility on January 16, 2009, and found no significant deficiencies. Your medical test site meets the requirements of Chapter 70.42 RCW, Chapter 246-338 WAC.

While on-site, I noted the following with respect to your handling of proficiency testing (PT) samples:

• There is a new ruling by CLIA that does not allow additional personnel to test the PT samples until after the test scores are received from the PT agency. My review of your records, under your current protocol, demonstrated that PT samples are routed to personnel in each site and tested for purposes of competency assessment. This testing was found to be performed before the receipt of the PT agency scores. In order for you to adhere with this ruling, you will need to have one person test the set of PT samples, complete the PT agency result form and submit it to the PT agency. You will need to wait until the official PT agency scores are received and then can route the samples to the other sites for competency assessment activities. You will need to revise your written procedure for handling/routing of proficiency testing samples and send me a copy of this revision.

If you have any questions or comments, please contact me at the above address or by telephone at (206) 418-5417.

Sincerely,

Kathy LaBeau, MT (ASCP)

Laboratory Surveyor and Consultant

Kathy LaBeau

cc:

Naomi Coulter

Keri Hanson

ipltre.596

Lab Director

Lab Contact

Lab Contact Email

Credential View Screen [update] 844360 Contact Planned Parenthood of the Great Warnings Audit **Northwest** SSN/FEIN **Public Cas** Address: Cont. Edu Federal ID 910686012 **Documents** Public Mail Renewal Mail Secretary Of StateNumber 578040516 Owners CLIA 50D0663561 [change public address] Owned By/ Contact Standing In-Business Planned Parenthood of Western Washington Central Exams **ORGANIZATION** Contact Type Region Experience Public File YES 4500 9th Ave NE Ste 324 Notes Mailing List Seattle, WA 98105-4778 Schools Supervises Supervised Legacy Librarian Application Comments: Other State Medical Test Site Categorized License [update] [form letter] MTSC.FS.00000038 Credential # **Credential Status ACTIVE** Audit Legacy License # -MTS-0038 Status Reason **ACTIVE** Docum Application Date **Amount Due** \$0.00 Workflo 12/30/2008 9:53:47 AM Кеу Мұ **Effective Date** 07/01/2007 **Date Last Activity** Fees Last Updated by **Expiration Date** 06/30/2009 System Certificate Sent Date Notes First Issuance Date Print D Last Date Of Contact Comp. Next Examination Date 02/28/2011 Renew Legacy Comments: Medica **User Defined License Data** Legacy **HIPDB** User Definable License Data [update] Medical Test Site Type Community Clinic Medical Test Site Region Region 2 MTS Category Category A Multiple Sites Yes MTS Lab Testing Personnel 1 **ARNP** MTS Lab Testing Personnel Quantity 1 1 MTS Lab Testing Personnel 2 On Job Training MTS Lab Testing Personnel Quantity 2 9

MICHAEL ROMO MS MT(ASCP)

MICHAEL ROMO

michael.romo@ppww.org

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0 Privilege / Exemption reason used:
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