



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
Seattle District  
Pacific Region  
22201 23rd Drive SE  
Bothell, WA 98021-4421

Telephone: 425-486-8788  
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November 4, 2003

**VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 04-08

Thomas O. Tiffany, PhD  
Chief Executive Officer  
Bourget Health Services, Inc.  
dba Pathology Associates Medical Laboratories  
110 West Cliff Avenue  
Spokane, Washington 99204

**WARNING LETTER**

Dear Dr. Tiffany:

During an inspection of your human organ and tissue testing facility located at 110 West Cliff Avenue, Spokane, Washington, on August 20-22, 2003, our investigator documented significant deviations of the regulations for human tissue intended for transplantation, as set forth in Title 21, Code of Federal Regulations (CFR) Part 1270, promulgated under the authority of Section 361 of the Public Health Service Act (PHS Act).

The observed deviations include the following:

1. Failure to follow manufacturer's instructions for infectious disease testing of donor specimens to determine suitability of human tissue for transplantation [21 CFR § 1270.21(a)], in that.
  - a) Three of 20 test runs for HBsAg were not incubated in accordance with the test kit manufacturer's instructions which required a 75-80 minute incubation period. These include samples [REDACTED] (35 minute incubation); [REDACTED] (74 minute incubation); and [REDACTED] (84 minute incubation period). These failures to follow procedures were not detected by your facility.
  - b) One of 20 test runs for anti-HIV-1/2 was not incubated in accordance with the manufacturer's instructions. Incubation was conducted for a total of 28 minutes rather than the required for 30-33 minutes for donor sample [REDACTED] during both the first and second incubations.

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2. Failure to follow written procedures for all significant steps in infectious disease testing [21 CFR § 1270.31(a)], in that:
  - a) All incubation time periods are not documented for all tests. For instance, the Organ Donor Workup Record Sheet is preprinted with a "NA" in the "2<sup>nd</sup> incubation start/end" block for both the HBsAg and anti-HBcore assays. In addition, the Organ Donor Workup Record Sheet is preprinted with a "NA" in the "3<sup>rd</sup> incubation start/end" block for both the anti-HCV and anti-HIV-1/2 assays. These incubation times are not documented as required by your firm's "[REDACTED] Organ Donor Procedure". Your facility was cited for this during a previous FDA inspection, yet you failed to implement an adequate corrective action, and the deviation continues.
  - b) The start and stop time for the o-phenylenediamine (OPD) solution was not recorded for 13 test runs (HBsAg (3), HBcore (3), anti-HCV (3), and anti-HIV-1/2 (4)) reviewed during the inspection as required by your firm's "[REDACTED] Organ Donor Procedure".
  
3. Failure to maintain records concurrently with the performance of each significant step in the performance of infectious disease screening and testing of donors of human tissue. Records are not accurate and indelible [21 CFR § 1270.33(a)], in that:
  - a) Correction tape was used on the "1<sup>st</sup> incubation end time" on the Organ Donor Workup Record Sheet for one of 20 test runs for HBsAg. The original time was obliterated and corrected to an incubation time of 35 minutes.
  - b) Correction tape was used on the "2<sup>nd</sup> step time of preparation" on the Organ Donor Workup Record Sheet for one of 20 test runs for anti-HIV-1/2. The correction tape obliterated the original time.
  - c) Correction tape was used on the "2<sup>nd</sup> step time of preparation" and "2<sup>nd</sup> incubation start/end" on the Organ Donor Workup Record Sheet for 2 of 20 test runs for HBsAg and anti-HBcore. The correction tape obliterated the original times.

The above-identified violations are not intended to be an all inclusive list of deficiencies at your facility. You are responsible for ensuring that your human tissue testing facility operates in compliance with Section 361 of the PHS Act and 21 CFR Part 1270. You are responsible for investigating and determining causes of the violations identified by FDA. You should take prompt action to correct these violations. Failure to do so may result in additional regulatory action without further notice. Such action may include, but is not limited to, an Order for Retention, Recall, and/or Destruction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted deviations and to prevent their recurrence. Include examples of any documentation such as revised written procedures, retraining records, or other records demonstrating corrective action. If corrective action cannot be completed within 15

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working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 22201 23<sup>rd</sup> Drive SE, Bothell, Washington 98021-4421, Attention: Lisa M. Althar, Compliance Officer.

Sincerely,

*Kristy D. Davis*  
for Charles M. Breen  
District Director

cc: Ryland Davis, President and CEO  
Sacred Heart Medical Center  
101 8<sup>th</sup> Street  
Spokane, Washington 99204