

July 18, 2008

Important Safety Information

BD Vacutainer® Blood Collection Tubes Containing Heparin

The FDA has recently requested that manufacturers of heparin containing products assure that the heparin used is analyzed for contamination using the following test methods: nuclear magnetic resonance (H-NMR spectroscopy) and capillary electrophoresis (CE). BD has implemented this test requirement with our suppliers and has received test results on the most recently supplied heparin raw material lots.

BD is supplying this information to users of BD Vacutainer® Blood Collection Tubes that contain lithium heparin to inform them that the product lots shown in the attached table have been confirmed to contain small amounts of the heparin contaminant Oversulfated Chondroitin Sulfate (OSCS).

The OSCS contaminant in the affected raw material lots of lithium heparin is reported to be less than 1% dry weight. BD is not aware of and has not received any reports of performance-related issues for these lots. In addition, BD has verified through testing that OSCS at the levels identified above, does not affect the anticoagulant performance of the lithium heparin in the BD Vacutainer® Blood Collection Tubes. BD also has tested 27 different chemistry analytes (glucose, potassium, sodium, chloride, CO₂, blood urea nitrogen (BUN), creatinine, uric acid, phosphorus, calcium, cholesterol, triglycerides, total protein, albumin, total bilirubin, alkaline phosphatase, gamma glutamyltransferase (GGT), aspartate aminotransferase (AST), alanine aminotransferase (ALT), lactate dehydrogenase (LDH), iron, magnesium, total T₃, creatine kinase (CK), amylase, high density lipoprotein(HDL), and ferritin) and no differences in performance between tubes made with contaminated and uncontaminated heparin were seen. Additionally, BD has now completed testing for thyroid stimulating hormone (TSH), Troponin I, Free T₄ and CK-MB and no differences in performance between tubes made with contaminated and uncontaminated heparin were seen. Detailed results can be found on our website www.bd.com/vacutainer. Interference tests for all blood gas parameters have not been performed because blood gas analysis is not within the intended use of BD Vacutainer® Blood Collection Tubes. BD recommends that users continue to be vigilant for unexpected results, particularly when they use known contaminated tubes, and promptly report any unexpected result to BD (and FDA using the electronic Medical Device Reporting (MDR) system at <http://www.fda.gov/cdrh/emdr/>).

Additionally, BD is working with our suppliers to further evaluate all heparin raw material lots utilized in BD Vacutainer® Blood Collection Tubes that are still within expiration date. BD is working with our suppliers to ensure the purity of heparin supply and to ensure

going forward that all BD products meet FDA requirements. As we obtain confirmation of the contamination status we will publish the information regarding any additional contaminated lots on our website www.bd.com/vacutainer.

As with all diagnostic products, you should use these products in accordance with the manufacturer's instructions and monitor the performance of these products in accordance with your routine quality control procedures. If you notice any unexpected results or have any additional questions, please contact BD Technical Service at 1-800-631-0174.
Very truly yours,

BD Diagnostics - Preanalytical Systems

| Product Description | Catalog Number | Lot Number |
|------------------------------------|----------------|------------|
| TUBE LIHEP PLH 13X75 4.0 SLBL GN | 365901 | 8080134 |
| TUBE LIHEP GC 10.25X64 3.0 PLBL GN | 366388 | 7344732 |
| TUBE LIHEP PLH 13X75 2.0 PLBL GN | 366664 | 7344768 |
| TUBE LIHEP PLC 13X75 3.0 PLBL GN | 366667 | 8080162 |
| TUBE LIHEP PLC 16X100 10.0 PLBL GN | 367880 | 7344840 |
| TUBE LIHEP PLC 16X100 10.0 PLBL GN | 367880 | 8080218 |
| TUBE LIHEP PLH 13X75 4.0 PLBL GN | 367884 | 7309962 |
| TUBE LIHEP PLH 13X75 4.0 PLBL GN | 367884 | 7309961 |
| TUBE LIHEP PLH 13X75 4.0 PLBL GN | 367884 | 7344841 |
| TUBE LIHEP PLH 13X75 4.0 PLBL GN | 367884 | 7344842 |
| TUBE LIHEP PLH 13X75 4.0 PLBL GN | 367884 | 7344844 |
| TUBE LIHEP PLH 13X75 4.0 PLBL GN | 367884 | 7309964 |
| TUBE LIHEP PLH 13X75 4.0 PLBL GN | 367884 | 8064486 |
| TUBE LIHEP PLH 13X75 4.0 PLBL GN | 367884 | 8064487 |
| TUBE LIHEP PLH 13X75 4.0 PLBL GN | 367884 | 8064488 |
| TUBE LIHEP PLH 13X75 4.0 PLBL GN | 367884 | 8080219 |
| TUBE LIHEP PLH 13X75 4.0 PLBL GN | 367884 | 8080220 |
| TUBE LIHEP PLH 13X75 4.0 PLBL GN | 367884 | 8080222 |
| TUBE LIHEP PLH 13X100 6.0 PLBL GN | 367886 | 7309965 |
| TUBE LIHEP PLH 13X100 6.0 PLBL GN | 367886 | 7344848 |
| TUBE LIHEP PLH 13X100 6.0 PLBL GN | 367886 | 8064489 |
| TUBE LIHEP PLH 13X100 6.0 PLBL GN | 367886 | 8080223 |
| TUBE PST PLH 13X75 3.0 PLBL L/GN | 367960 | 7309983 |
| TUBE PST PLH 13X75 3.0 PLBL L/GN | 367960 | 7309981 |
| TUBE PST PLH 13X75 3.0 PLBL L/GN | 367960 | 7344857 |
| TUBE PST PLH 13X75 3.0 PLBL L/GN | 367960 | 7344858 |
| TUBE PST PLH 13X75 3.0 PLBL L/GN | 367960 | 7344859 |
| TUBE PST PLH 13X75 3.0 PLBL L/GN | 367960 | 8064506 |
| TUBE PST PLH 13X75 3.0 PLBL L/GN | 367960 | 8064507 |
| TUBE PST PLH 13X75 3.0 PLBL L/GN | 367960 | 8064508 |
| TUBE PST PLH 13X75 3.0 PLBL L/GN | 367960 | 8064510 |
| TUBE PST PLH 13X75 3.0 PLBL L/GN | 367960 | 8080233 |

| Product Description | Catalog Number | Lot Number |
|------------------------------------|----------------|------------|
| TUBE PST PLH 13X75 3.0 PLBL L/GN | 367960 | 8080234 |
| TUBE PST PLH 13X100 3.5 PLBL L/GN | 367961 | 7344861 |
| TUBE PST PLH 13X100 3.5 PLBL L/GN | 367961 | 8080237 |
| TUBE PST PLH 13X100 4.5 PLBL L/GN | 367962 | 7309990 |
| TUBE PST PLH 13X100 4.5 PLBL L/GN | 367962 | 7309988 |
| TUBE PST PLH 13X100 4.5 PLBL L/GN | 367962 | 7309986 |
| TUBE PST PLH 13X100 4.5 PLBL L/GN | 367962 | 7344862 |
| TUBE PST PLH 13X100 4.5 PLBL L/GN | 367962 | 7344864 |
| TUBE PST PLH 13X100 4.5 PLBL L/GN | 367962 | 7344865 |
| TUBE PST PLH 13X100 4.5 PLBL L/GN | 367962 | 8064513 |
| TUBE PST PLH 13X100 4.5 PLBL L/GN | 367962 | 8064514 |
| TUBE PST PLH 13X100 4.5 PLBL L/GN | 367962 | 8064516 |
| TUBE PST PLH 13X100 4.5 PLBL L/GN | 367962 | 8080239 |
| TUBE PST PLH 13X100 4.5 PLBL L/GN | 367962 | 8080240 |
| TUBE PST PLH 13X100 4.5 PLBL L/GN | 367962 | 8080241 |
| TUBE PST PLH 13X100 4.5 PLBL L/GN | 367962 | 8080242 |
| TUBE PST PLH 13X100 4.5 SLBL L/GN | 367963 | 7344868 |
| TUBE PST PLH 13X100 4.5 SLBL L/GN | 367963 | 8064519 |
| TUBE PST PLC 16X100 8.0 PLBL GN/GR | 367964 | 7344869 |
| TUBE PST PLC 16X100 8.0 PLBL GN/GR | 367964 | 8064520 |
| TUBE PST PLC 16X100 8.0 PLBL GN/GR | 367964 | 8080243 |
| TUBE PST PLC 13X75 3.0 PLBL GN/GR | 368056 | 7344872 |
| TUBE PST PLC 13X75 3.0 PLBL GN/GR | 368056 | 8080247 |
| TUBE PST PLC 16X100 4.0 PLBL GN/GR | 368824 | 7344884 |
| TUBE PST PLC 16X100 4.0 PLBL GN/GR | 368824 | 8080258 |

Additional lots confirmed to contain less than 1% OSCS contaminant.

| Product Description | Catalog Number | Lot Number |
|-----------------------------------|----------------|------------|
| TUBE LIHEP PLH 13X75 4.0 PLBL GN | 367884 | 8122606 |
| TUBE LIHEP PLH 13X100 6.0 PLBL GN | 367886 | 8122607 |
| TUBE LIHEP PLH 13X100 6.0 PLBL GN | 367886 | 8161427 |
| TUBE PST PLH 13X75 3.0 PLBL L/GN | 367960 | 8122631 |
| TUBE PST PLH 13X100 4.5 PLBL L/GN | 367962 | 8122636 |
| TUBE PST PLH 13X100 4.5 PLBL L/GN | 367962 | 8122637 |

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