



Date: February 4, 2004

Subject: **BD Diagnostics Position Statement on  
Control of BSE Risk Materials in our Products**

Over the years, BD Diagnostics has continuously worked to limit the risk of BSE prions in our products. We have maintained our policy of securing bovine raw materials strictly from designated non-BSE countries. BD Diagnostics works closely with our suppliers to provide extensive documentation for our products including Certificates of Analysis ([www.bdregdocs.com](http://www.bdregdocs.com)) and Certificates of Suitability. For our bioprocessing clients, we have created a wide variety of additional options for reducing BSE risks, including but not limited to:

- Animal-free formulations
- Dedicated processing for animal-free formulations
- The Autonutrient™ Media Design Service
- Select country of origin sourcing (i.e., Australia / New Zealand only)
- Bovine-free meat-based media formulations
- Category IV Only bovine formulations and other custom products as requested

With the relatively recent exclusion of Canadian sources of bovine materials per our BD Diagnostics policy and the news of the importation of a BSE-infected animal into the United States (US), we have taken the time to re-evaluate our policies and perform a risk assessment. Based upon this assessment, we have determined that our current policies and practices for BSE risk reduction - as well as the complement of products and services to meet the requirements of our various customer types – are both ample and sound.

However, our policy of sourcing only from BSE-free countries becomes untenable if the US status were to change from its current designation in the near future. BD Diagnostics offers a portfolio of finished goods containing bovine raw materials that number in the thousands. These products address a variety of applications including diagnostic microbiology, research and bioprocessing. Identifying, contracting and validating raw materials from new suppliers for all of our finished goods with bovine parts would be both a lengthy and costly process. Our evaluation shows that substantially increasing the costs of most of our products in the future by switching to New Zealand and/or Australia only sources is not desirable for the majority of our diagnostic microbiology customers since it yields only limited risk-reduction and has an insignificant impact on safety for those applications.

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Thus, we are signaling a specific change to our policy that will result in managing BSE risks in accordance with a given product's intended use. Specifically, we will continue to source bovine materials only from BSE-free countries **and** from the US, Australia and New Zealand, regardless of their designation, for the majority of our diagnostic products. We will also continue to use multi-use equipment in the manufacture of all formulations, other than those designated "Animal Free" that are produced in our DCM (dehydrated culture media) Plant's dedicated manufacturing suite and equipment. Therefore, those customers that require additional safeguards in the event the US, Australia and/or New Zealand have a change to their BSE status (especially our clients in the field of bioprocessing and those performing media fills) are encouraged now to take advantage of the many options for controlled raw material origin or animal-free solutions that BD Diagnostics has offered for years. Animal-free products can be processed in a dedicated animal-free environment. Custom products can be designed and managed to meet specific customer needs.

For further details, please see the attached BD Diagnostics Revised Animal Origin Policy Brief. For more information on our animal-free or custom products, please send your inquiries to [BSE\\_Inquiry@bd.com](mailto:BSE_Inquiry@bd.com).



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