c7321_510251

This pr
with th
Manufacturing Practices (cGMP) contained in Title 21 Part 820 of the Code of Federal Regulations (CFR). Th
company's manufacturing establishments are registered, and its medical devices are listed with the FDA. Hardy
Diagnostics' quality management system is certified to ISO 13485 for medical devices.

Representative samples of the powder lot were tested and found to meet the specifications listed on this certifi
and published on the Instructions for Use (IFU) for this product as located on the Hardy Diagnostics website,
applicable. In addition, this lot conforms to the quality control standards listed in the reference document, whe
indicated. End-users of commercially prepared culture media and reagents should perform QC testing in accor
with applicable government regulatory agencies and in compliance with accreditation requirements. Hardy Diag
recommends end-user to check for signs of contamination and deterioration and, if dictated by laboratory qual
control procedures or regulation, perform QC testing to demonstrate a positive reaction and/or a negative react
applicable.

Dehydrated culture media requires further preparation and/or supplementation in order to meet the performanc
characteristics indicated below. Unless otherwise listed, this product is not labeled as sterile and requires additi
processing to achieve the user desired sterility assurance level.

Performance Testing

Test Organism		
Salmonella en		th; red colonies with black cente
Shigella flexne		th; red to pink colonies
Enterococcus faecalis		Partial to complete inhibition; small cl

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