

## CERTIFICATE OF ANALYSIS

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**Product** : Owren's Buffer

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**Code No.** : 5375

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**Lot No.** : 21444972

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**Expiry** : 2019-01

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**Storage** : As indicated on packaging.

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**Testing** : PASS

Testing has shown that this material meets Quality Control specifications.

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**Quality Control Release Date:** 01 Mar 2017

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**Signed:** Carol J Sandercock

**Date:** 01 Mar 2017

A handwritten signature in black ink, appearing to read "C Sandercock", written over a light blue horizontal line.

**Regulatory Affairs & Quality Assurance Officer**

Note: N/A = Not Applicable

### Declaration

This product was manufactured and tested in compliance with the directives of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, ISO 13485:2003 and EN ISO 13485:2012.

Helena Biosciences are accredited to ISO 13485:2003 and EN ISO 13485:2012 for the manufacture of medical devices. Copies of this certification are available upon request.

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