



Lloyd's Register  
LRQA

## EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM

**In accordance with the requirements of the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the Medical Devices Regulations 2002, UK Statutory Instrument 2002 No. 618**

This is to certify that the Quality Management System of:

**Biochrom Ltd  
1020 Cambourne Business Park,  
Cambourne, Cambridge,  
United Kingdom**

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown on the attached certificate schedule.

Approval is subject to the maintenance of the quality system in accordance with the requirements of the above Directive and Regulations.

Authorisation is hereby given to use the LRQA Notified Body Registration Number in accordance with the requirements of the specified Directives/Regulations in relation to the products as identified above.

Certificate No: LRQ 0890333/C  
Original Approval: 25 May 2004  
Current Certificate: 1 November 2015  
Certificate Expiry: 31 October 2018

LRQA Notified Body Number 0088

Issued by: Lloyd's Register Quality Assurance Limited



## EC CERTIFICATE – FULL QUALITY ASSURANCE SYSTEM CERTIFICATE LRQ 0890333/C SCHEDULE

has been assessed against the requirements of Annex IV of the In Vitro Diagnostic Medical Devices Directive 98/79/EC, and the Medical Devices Regulations 2002 and conforms to the requirements for the products shown below:

**Biochrom Ltd**  
**1020 Cambourne Business Park,**  
**Cambourne, Cambridge,**  
**United Kingdom**

### Annex II List B Products

Ultra Physiological Fluid Kit	Cat. Ref. 80-2117-77
Ultra Physiological Routine Kit	Cat. Ref. 80-6000-06
Biochrom Lithium Buffer Start-up Kit	Cat. Ref. 80-6000-16
Biochrom Lithium Buffer Routine Kit	Cat. Ref. 80-6000-17

Containing:

- |                                 |                      |
|---------------------------------|----------------------|
| • Lithium Buffer 1              | Cat. Ref. 80-2038-15 |
| • Lithium Buffer 2              | Cat. Ref. 80-2038-16 |
| • Lithium Buffer 3              | Cat. Ref. 80-2099-83 |
| • Lithium Buffer 4              | Cat. Ref. 80-2097-18 |
| • Lithium Buffer 5              | Cat. Ref. 80-2037-69 |
| • Lithium Regeneration Buffer 6 | Cat. Ref. 80-2038-20 |

Ultra Ninhydrin Kit 2L	Cat Ref: 80-2118-30
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Ultra Ninhydrin Kit 8L	Cat Ref: 80-2117-76
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Both containing:

- |                            |                      |
|----------------------------|----------------------|
| • Ultra Ninhydrin Solution | Cat. Ref. 80-2117-64 |
| • Ultrasolve Plus          | Cat. Ref. 80-2117-65 |

EZ Nin Reagent Kit 2L	Cat. Ref. 80-6000-13
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EZ Nin Reagent Kit 4L	Cat. Ref. 80-6000-14
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EZ Nin Reagent Kit 8L	Cat. Ref. 80-6000-15
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Containing:

- |                  |                      |
|------------------|----------------------|
| • EZ Nin Reagent | Cat. Ref. 80-6000-12 |
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Schedule Issue: 01

Date of Schedule Issue: 1 November 2015

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