

AXIS-SHIELD DIAGNOSTICS Ltd.
Manufacturing Department

Axis Shield Diagnostics Ltd.
 The Technology Park,
 Dundee, DD2 1XA
 United Kingdom

QC-FHYB100-05

Certificate of Analysis for 3 Reagent Enzymatic HCY Kit

Part Number:	FHYB100
Customer:	Beckman-Coulter
Lot Number:	802905256
Expiry Date:	2016-10-26


Components of Kit:	Description	Lot No.
FHYB110	Enzymatic HCY Reagent 1	802905527
FHYB120	Enzymatic HCY Reagent 2	802905552
FHYB130	Enzymatic HCY Reagent 3	802905553
FHRK140	Enzymatic HCY Calibrator 0	802904694
FHRK150	Enzymatic HCY Calibrator 28	802904492

Under test	Assay 1	Assay 2	Specification - Single Assay	Control Grand Mean	Specification - QC Release	Pass/Fail against QC Release
FHCY220, Low Kit Control - Mean μ M	7.1	6.8	3.6 - 9.4	6.94	4.61 - 8.39	Pass
FHCY230, Medium Kit Control - Mean μ M	12.4	12.1	8.7 - 15.7	12.24	9.99 - 14.41	Pass
FHCY240, High Kit Control - Mean μ M	25.7	24.9	19.1 - 32.0	25.29	21.52 - 29.68	Pass

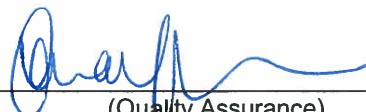
Trend analysis performed and is acceptable (circle as applicable): YES / NO

The above Axis-Shield product has been tested by Manufacturing and meets / does not meet (Circle as appropriate) all final QC specifications.

This product is / is not (Circle as appropriate) suitable for use until the stated expiry date.

Authorised Signatory: 
 (Manufacturing)

Date: 2015/09/17
 (YYYY/MM/DD)

Authorised Signatory: 
 (Quality Assurance)

Date: 2015-09-17
 (YYYY/MM/DD)

AXIS-SHIELD DIAGNOSTICS LIMITED

Release for Packing

3-Reagent Enzy HCY for Synnchron Reagent FHYB100

Kit Lot No	802905256	Expiry Date	2016-10-26
Batch Size	241		
Customer	Beckman Coulter		

Description

Description	Part Number	Lot No.	Expiry Date
3-Reagent Enzy HCY for Synnchron Rgt 1	FHYB110	802905527	2016-10-26
3-Reagent Enzy for Synnchron Rgt	FHYB120	802905552	2016-10-27
3-Reagent Enzy HCY for Synnchron Rgt	FHYB130	802905553	2016-10-27
Axis-Shld 2 Reag Enzymatic HCY Cal 0 µM	FHRK140	802904694	2016-11-17
Axis-Shd 2 Reag Enzymatic HCY Cal 28 µ M	FHRK150	802904492	2016-11-17

3-Reagent Enzy HCY for Synnchron FHYB100 Lot No. 802905256 (Is) Is not released for packing

Signed Mike Barr Date 2015/09/17
 (Manufacturing)