

SURVEY V4:2011:4C & 4D HSV SEROLOGY

Report prepared and collated by: RCPA Serology QAP
Review discussion for and on behalf of RCPA Serology QAP by:
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Kit Performance

It is up to all users to form their own opinion or conclusions on each kit's performance based on the accumulation of data and information that is supplied by this survey, and other information available to the participant. A variety of samples are used in this Program (straight, undiluted serum; diluted serum and pooled serum) and this can sometimes impact on results and performance of some kits. With serum specimens, occasional artefactual problems are encountered with some kits due to changes in the matrix caused by rethrombinisation of plasma or dilution.

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Confidentiality

RCPA Quality Assurance Programs Pty Ltd keeps all participant details confidential. Such details will not be disclosed to a third party, unless required by legislation, without the prior written consent of the participant.

Clinical Notes

The "Clinical Notes" were created so as to highlight particular issues relating to interpretation of serological results. They do not necessarily reflect the clinical history of the patient from whom the sample was obtained.

4C After a number of sexual encounters this patient wants to know whether he has had HSV.

4D This patient has a history of herpetic lesions but none active at presentation. She wants to confirm HSV infection.

Request

Please test these sera for Herpes Simplex and treat in the same manner as routine patient samples.

Specimen Details

Specimens are of human origin and tested negative for hepatitis B surface antigen, hepatitis C antibody and HIV.

(Ref. 2011 SQA Program Plan section V4:2011)

4C is a serum sample that tested positive for HSV IgG, HSV 1 IgG, HSV 2 IgG and negative for HSV IgM and HSV 1 & HSV 2 IgM antibodies by EIA and Western Blot.

4D is a serum sample that tested positive for HSV IgG and negative for HSV 1 IgG, HSV 2 IgG and HSV IgM by EIA. This specimen was positive for HSV 1 IgG and HSV 2 IgG and negative for HSV 1 IgM and HSV 2 IgM when tested by Western Blot.

Source: SEALS, Prince of Wales Hospital, NSW.

Pre-issue testing: Laverty Pathology, North Ryde, NSW and ICPMR, Westmead Hospital, NSW.

Analysis of Results

For information on "Analysis of Results" please refer to your Serology QAP Participation Booklet for the current year. The personalised Assessment Report is an indicator for participants to review their results and evaluate their own performance as 'Satisfactory' or 'Unsatisfactory'.

Robust Statistics

Analysis of Results using Robust Statistics is performed on user groups of five (5) or more participants using the same units and are **now available on your personalised Assessment Report.**

In order to calculate the statistics as accurately as possible, results that are presented as < or > are entered into the calculations as the next whole number. For example, <10 is entered into the calculation as 9 and >500 is entered as 501.

To view robust statistics of user groups other than your own, use the RCPA Serology QAP website: <http://www.rcpaqap.com.au/serology> Log into the 'Member Services' section and go to 'Dynamic Graphs of Results'.

Results Returned by Participants

72 participants returned results for Herpes Simplex serology.

Survey Results V4:2011 Herpes Simplex Virus

Herpes Simplex 1 & 2 IgG - Specimen 4C

pos: 21 = 100.00%
 Total Results =21
Consensus: pos

Herpes Simplex 1 & 2 IgG - Specimen 4D

neg: 21 = 100.00%
 Total Results =21
Consensus: neg

Herpes Simplex - 1 IgG - Specimen 4C

equ: 2 = 4.08%
 neg: 3 = 6.12%
 pos: 44 = 89.80%
 Total Results =49
Consensus: pos

Herpes Simplex - 1 IgG - Specimen 4D

neg: 44 = 89.80%
 pos: 5 = 10.20%
 Total Results =49
Consensus: neg but not scored – see below

Herpes Simplex - 2 IgG - Specimen 4C

equ: 4 = 7.41%
 neg: 17 = 31.48%
 pos: 33 = 61.11%
 Total Results =54
 Consensus: No

Herpes Simplex - 2 IgG - Specimen 4D

neg: 53 = 98.15%
 pos: 1 = 1.85%
 Total Results =54
Consensus: neg

Herpes Simplex 1 & 2 IgM - Specimen 4C

neg: 35 = 100.00%
 not tested: Excluded
 Total Results =35
Consensus: neg

Herpes Simplex 1 & 2 IgM - Specimen 4D

neg: 37 = 100.00%
 Total Results =37
Consensus: neg

Herpes Simplex - 1 IgM - Specimen 4C

neg: 8 = 100.00%
 Total Results =8
Consensus: neg

Herpes Simplex - 1 IgM - Specimen 4D

neg: 8 = 100.00%
 Total Results =8
Consensus: neg

Herpes Simplex - 2 IgM - Specimen 4C

neg: 8 = 100.00%
 Total Results =8
Consensus: neg

Herpes Simplex - 2 IgM - Specimen 4D

neg: 8 = 100.00%
 Total Results =8
Consensus: neg

Herpes Simplex CFT - Specimen 4C

AC: Excluded
 equ: 1 = 50.00%
 pos: 1 = 50.00%
 Total Results =2
 Consensus: No

Herpes Simplex CFT - Specimen 4D

neg: 3 = 100.00%
 Total Results =3
 Consensus: Insufficient data (less than 5 results)

Specimen 4D was not scored for Herpes Simplex 1 IgG assay because most of the out of consensus results are within one user group and appear to be kit related.

Participants 21439, 89061 and 89255 should review their results for Specimen 4D.

Participants 31234 and 89278 results for Specimens 4C and 4D appear reversed or an error occurred when transcribing the results.

Inconsistencies in this survey

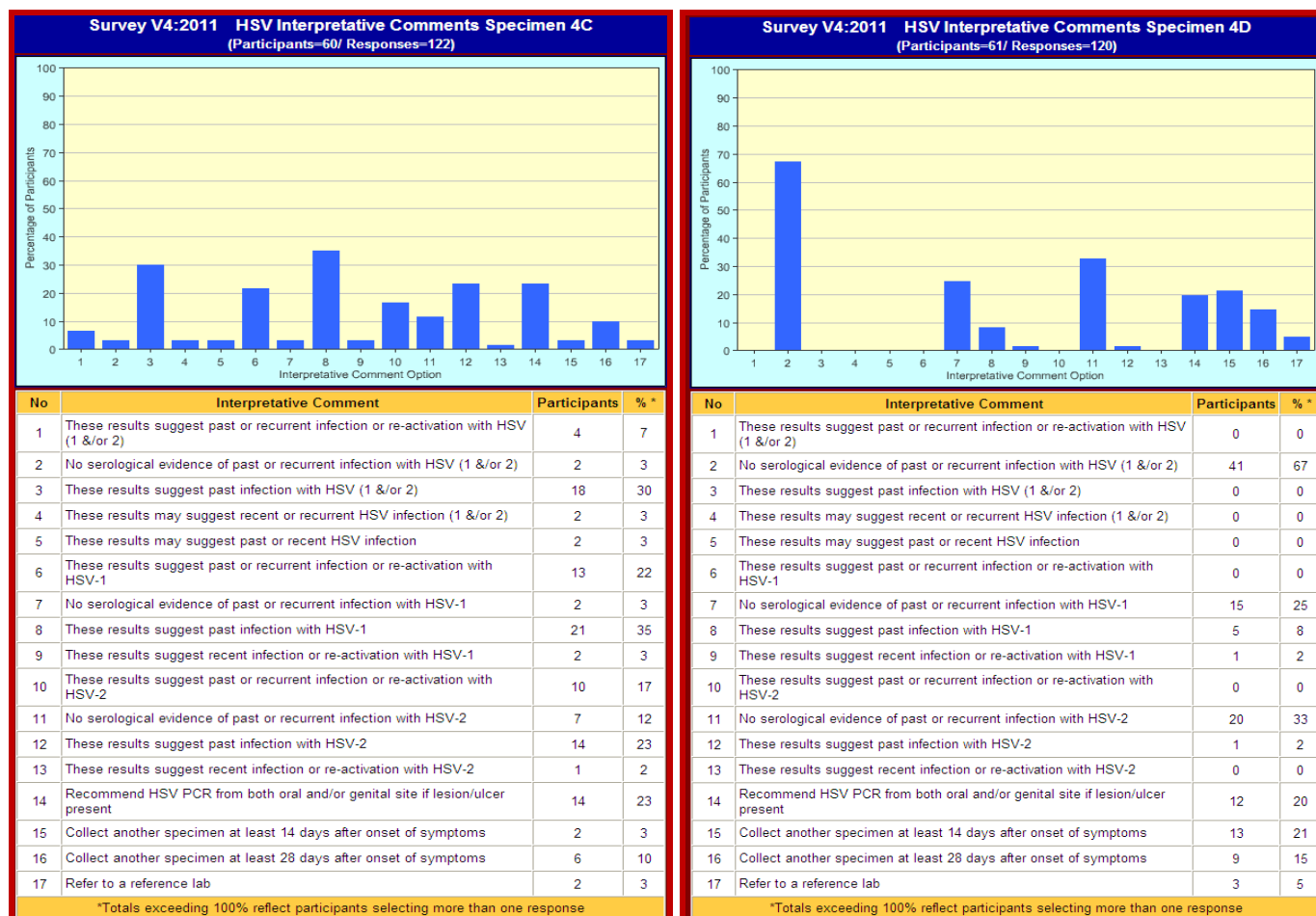
HSV IgG	Participant	Comment
Test Group	89115	Units not provided.
HSV-1 IgG	Participant	Comment
Specimen 4C	31234	Results inconsistent with the consensus; specimens appear to be reversed.
	61247	Result inconsistent with the consensus.
	89075	Result inconsistent with the consensus.
	89155	Result inconsistent with the consensus. An error appears to have occurred when transcribing the result.
	89278	Results inconsistent with the consensus; specimens appear to be reversed.
Specimen 4D	89255	Values appear to be elevated.
Test Group	21292	Units appear inconsistent with cut-off and result values reported.
	21721	Units appear inconsistent with the cut-off value provided.
	80021	Units not provided.
	89075	The cut-off is inconsistent with SQAP definition & kit insert for a value above which is positive.
	89129	The cut-off is inconsistent with SQAP definition & kit insert for a value above which is positive.
	89278	Cut-off value is inconsistent with the units reported.
HSV-2 IgG	Participant	Comment
Specimen 4D	31234	Result inconsistent with the consensus. An error appears to have occurred when transcribing the result.
Test Group	21292	Units appear inconsistent with cut-off and result values reported.
	21439	The cut-off is inconsistent with SQAP definition & kit insert for a value above which is positive.
	31433	Other users of the same lot number have a different expiry date.
	80021	Units not provided.
	89061	The cut-off is inconsistent with SQAP definition & kit insert for a value above which is positive.
	89129	Units appear inconsistent with the cut-off value provided.
	89130	Units appear inconsistent with the cut-off value provided.
	89255	The cut-off is inconsistent with SQAP definition & kit insert for a value above which is positive.
	89278	Units appear inconsistent with cut-off and result values reported.
HSV IgM	Participant	Comment
Test Group	21721	Units appear inconsistent with the cut-off value provided.
	51077	Units appear inconsistent with the cut-off value provided.
	83667	The cut-off is inconsistent with SQAP definition & kit insert for a value above which is positive.
	89129	Kit details entered in 'Other' section. Please use drop down list.

Inconsistencies in this survey (Cont'd)

HSV IgM	Participant	Comment
Test Group	89227	Cut-off value is inconsistent with the units reported.
	89278	Cut-off value is inconsistent with the units reported.
	89278	Other users of the same lot number have a different expiry date.
HSV-1 IgM	Participant	Comment
Test Group	89130	Units appear inconsistent with the cut-off value provided.
	89155	Units appear inconsistent with the cut-off value provided.
HSV-2 IgM	Participant	Comment
Test Group	89130	Units appear inconsistent with the cut-off value provided.
HSV CFT	Participant	Comment
Specimen 4C	21375	Result assigned is inconsistent with the cut-off and result value provided.

Interpretative Comments

Combination responses have been split into their appropriate option – for example, if a participant chose 4 & 6, they are counted once in each of those options. % is based on the total number of participants who provided comments and not the total number of comments. Therefore, the total % adds to more than 100%.



Extra Comments for HSV

41302	4C: If early primary infection with HSV2 is suspected, a second sample should be submitted, as the development of HSV2 IgG antibodies can take up to 6 weeks following exposure, may not occur in 5-20% of patients or alternatively, may be lost at a rate of 5-10% per year.
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Review discussion prepared by: David Dickeson, Serology, Centre for Infectious Diseases & Microbiology, ICPMR, CIDMLS Westmead, NSW, Australia

Overview

All participants testing group specific combined HSV-1 and HSV-2 IgG reported positive IgG for Specimen 4C and negative IgG for Specimen 4D while most participants reported HSV-1 IgG positive (90%) and HSV-2 IgG positive (61%) for Specimen 4C and both HSV-1 (90%) and HSV-2 IgG (98%) negative for Specimen 4D. No IgM was detected in either specimen.

Interpretation of Results by Method and Comment

Specimen 4C

When tested by western immunoblot, this specimen showed type specific-IgG positive bands for HSV-1 and for HSV-2 and was IgM negative for both HSV-1 and HSV-2. The most appropriate comment would be: "These results suggest past infection with HSV-1 and HSV-2". As IgM is often not detectable after a recurrent infection or re-activation comments 6 and 10 would also be appropriate.

I. HSV group antibody assays:

- (a) All 21 participants demonstrated antibodies positive for total HSV IgG and all 35 gave negative results for total HSV IgM antibodies by EIA. The most appropriate comment should be: "These results suggest past infection with HSV".
- (b) For those participants that demonstrated only total HSV IgG antibodies positive and did not test for total IgM antibodies, the comment should be: "These results may suggest past or recent HSV infection".

II. HSV type specific assays:

Ninety percent (44/49) of participants reported positive results for type specific HSV-1 IgG and 33 of 54 (61%) positive HSV-2 type specific IgG but the latter with no consensus. The majority of participants (16/49 for HSV-1 and 19/54 for HSV-2) used Focus Diagnostics EIA kits, 8 Euroimmun, 4 Novagnost, 3 Vital Diagnostics, 7 other EIAs, 5 automated chemiluminescent methods, 2 multiplex, 1 IFAT and 3 immunoblots.

Those reporting HSV-2 results that did not agree with the majority included negative results from 4 of 5 DiaSorin Liaison users, 1 of 8 Euroimmun, 3/19 Focus and single users of EIAs from Biokit, BioRad, Genzyme Virotech, Kalon Biological, Ridascreen and Trinity Biotech. Only eight tested HSV-1 IgM and HSV-2 IgM with all participants reporting negative results. With these results the most appropriate comment should be as follows: "These results suggest past or recurrent HSV-1 and HSV-2 infection".

Specimen 4D

When tested by western immunoblot this specimen showed negative type specific-IgG for both of HSV-1 and HSV-2 and negative type specific IgM for both HSV-1 and HSV-2.

The most appropriate comment would be: "No serological evidence of past or recurrent infection with HSV-1 or HSV-2."

I. HSV group antibody assays:

- (a) All 21 participants (100%) correctly reported negative total HSV IgG and all 37 participants demonstrated no total HSV IgM by EIA. The most appropriate comment should be: "No serological evidence of past or recurrent infection with HSV."
- (b) For those participants that only tested total HSV IgG and did not test IgM by EIA, the most appropriate comment should be: "No serological evidence of past infection with HSV."

II. HSV type specific assays:

Forty-four of 49 participants (90%) reported type specific IgG negative for HSV-1 and 53 of 54 participants (98%) showed type specific IgG was negative for HSV-2. All three users of the DiaSorin Liaison gave positive results for HSV-1 IgG as did one of eight using Euroimmun (31234) and one of 16 Focus EIA users (89278). These latter two participants may have mixed up their results. Only one (31234) of 8 participants using Euroimmun EIA kits gave a positive HSV-2 IgG result against the consensus. All 8 participants tested type specific IgM as negative for HSV-1 and specific IgM negative for HSV-2 by EIA. The most appropriate comment should be: "No serological evidence of past or recurrent infection with HSV-1 or HSV-2." Recollection 14 to 28 days after onset of symptoms may also be appropriate.

Comments

Type specific HSV serology still presents problems in these surveys even though the majority of participants agreed with the consensus. Those using the DiaSorin Liaison should check with the manufacturer as to why their results differed from so many other methods including immunoblots.

References

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Survey V4:2011:4C & 4D Herpes Simplex Virus – Summary

Part	Specimen 4C								Specimen 4D							
	HSV IgG	HSV-1 IgG	HSV-2 IgG	HSV IgM	HSV-1 IgM	HSV-2 IgM	CFT	Interp	HSV IgG	HSV-1 IgG	HSV-2 IgG	HSV IgM	HSV-1 IgM	HSV-2 IgM	CFT	Interp
21092		pos	neg					6,11		neg	neg					7,11
21229	pos	pos	pos	neg	neg	neg		6,10	neg	neg	neg	neg	neg	neg		2,16
21267	pos			not tested				3	neg			neg				2,15
21292		pos	pos	neg				6,10,14		neg	neg	neg				2,16
21347	pos			neg				4,14	neg			neg				2,14,16
21375		pos	pos	neg			AC	1		neg	neg	neg			neg	2
21398	pos							5	neg							2
21401		pos	pos					6,10,14		neg	neg					2,14,16
21412	pos			neg				3	neg			neg				2,15
21439		pos	neg					8,9,11		pos	neg					8,9,11,17
21500		pos	pos					6,10		neg	neg					7,11
21624		pos	neg		neg	neg	equ	8,14		neg	neg		neg	neg	neg	2,14,15
21721		pos	neg	neg				8		neg	neg	neg				2,15
21763		pos	pos	neg				3		neg	neg	neg				2,14
29033		pos	neg	neg				8		neg	neg	neg				2
29058		pos	pos	neg				8,12		neg	neg	neg				7,11
31008	pos			neg				3	neg			neg				2
31126	pos	pos	pos	neg				3,8,12	neg	neg	neg	neg				2,7,11,15
31221		pos	pos	neg				8,12,16		neg	neg	neg				2,16
31234		neg	neg	neg				7,11		pos	pos	neg				8,12
31369	pos	pos	pos	neg				8,12	neg	neg	neg	neg				2
31378	pos							3,14	neg							2
31433		pos	pos					1		neg	neg					2
41018		pos	pos					6,10		neg	neg					7,11
41133		pos	pos					6,10		neg	neg					7,11
41183		pos	pos	neg				3,14,16		neg	neg	neg				2,14,16
41302		pos	neg					8,11,14,16		neg	neg					2,14,16
51077		pos	pos	neg				8,12,14,16		neg	neg	neg				7,11,14,16
59006		pos	pos	neg				8,12		neg	neg	neg				2,15
61100		pos	pos					6,10,14,16,17		neg	neg					7,11,14,16
61247		equ	pos					6,12,14		neg	neg					2,14
61253		pos	neg	not tested				6,11		neg	neg	neg				2,7,11
61455		pos	pos					1		neg	neg					2
80021		pos	pos							neg	neg					
81325	pos							18	neg							2
83667		pos	equ	neg				8		neg	neg	neg				2
89012	pos			neg				3	neg			neg				2
89019	pos			neg				3,14	neg			neg				2,14,15

Survey V4:2011:4C & 4D Herpes Simplex Virus – Summary

Part	Specimen 4C								Specimen 4D							
	HSV IgG	HSV-1 IgG	HSV-2 IgG	HSV IgM	HSV-1 IgM	HSV-2 IgM	CFT	Interp	HSV IgG	HSV-1 IgG	HSV-2 IgG	HSV IgM	HSV-1 IgM	HSV-2 IgM	CFT	Interp
89035		pos	pos					8,9,12,13,15		neg	neg					7,11,15
89036	pos			neg				3	neg			neg				2
89041		pos	pos	neg				3		neg	neg	neg				7,11
89045		pos	neg					6		neg	neg					2
89046				neg			pos	3				neg			neg	2
89051		pos	pos		neg	neg		6,8,10,12,14,15		neg	neg		neg	neg		7,11,14,15
89058		pos	pos	neg				3,5,8,12		neg	neg	neg				2,7,11,15
89061		pos	neg	neg				8		pos	neg	neg				8
89075		neg	pos					7,12		neg	neg					7,11
89078					neg	neg		17					neg	neg		17
89101	pos			neg				3,14	neg			neg				2,15
89106		pos	pos		neg	neg				neg	neg		neg	neg		
89107			pos			neg		12			neg			neg		11
89114			neg					11			neg					11,17
89115	pos								neg							
89125	pos			neg				3	neg			neg				2
89129		pos	pos	neg				1,3,4		neg	neg	neg				2
89130		pos	neg		neg	neg				neg	neg		neg	neg		
89144				neg								neg				
89148	pos	pos	neg	neg	neg	neg		8,11	neg	neg	neg	neg	neg	neg		2
89152	pos		neg	neg					neg		neg	neg				
89155		equ			neg					neg			neg			
89212		pos	neg							neg	neg					
89227				neg				2				neg				2
89236			pos					10			neg					11,15
89248			pos								neg					
89255	pos	pos	pos	neg				3,8,12	neg	pos	neg	neg				2,8,11
89278		neg	neg	neg				2		pos	neg	neg				8
89299	pos	pos	equ	neg				3,8,16	neg	neg	neg	neg				2,15
89300			neg								neg					
91119	pos	pos	pos					6,10	neg	neg	neg					2
91267		pos	equ					8,12,14		neg	neg					7,11,14
91317		pos	equ					8		neg	neg					2
91487		pos	pos					18		neg	neg					18

Survey V4:2011:4C & 4D Herpes Simplex Virus 1&2 IgG

Part	Manufacturer	Kit Name	Method	Automation	Lot No.	Expiry Date	Units	Cut Off	Value 4C	Result 4C	Value 4D	Result 4D
89115	DiaSorin	Liaison HSV 1/2 IgG	ChLIA	Liaison	75050	Jul-12	N/A	1.1	20.9	pos	<0.5	neg
89152	DiaSorin	Liaison HSV 1/2 IgG	ChLIA	Liaison	75049	Apr-12	S/CO	1.1	25.4	pos	0.5	neg
89255	DiaSorin	Liaison HSV 1/2 IgG	ChLIA	Liaison	75050	Dec-11	S/CO	0.9	26	pos	0.5	neg
31008	Genzyme Virotech	HSV Screen	ELISA	-	124-01	Jan-12	S/CO	1.1	2.41	pos	0.087	neg
89019	Genzyme Virotech	HSV Screen	ELISA	-	125-01	Oct-12	OD	0.834	1.619	pos	0.387	neg
89125	Genzyme Virotech	HSV Screen	ELISA	-	125-01	Oct-12	S/CO	1.1	2.109	pos	0.217	neg
89012	IBL	Herpes Simplex Virus 1-2 IgG	ELISA	-	HSVG-046	Feb-12	OD	0.253	0.536	pos	0.055	neg
89036	IBL	Herpes Simplex Virus 1-2 IgG	ELISA	-	HSVG-046	Feb-12	OD	0.366	0.768	pos	0.034	neg
89299	In house	in house	IFAMA	Manual	IFAMA	NA	titre	16	128	pos	<16	neg
81325	Ridascreen	HSV 1+2 IgG	EIA	-	12390	Feb-12	OD	0.36	1.381	pos	0.065	neg
21267	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgG	EIA	Evolis	40484	Apr-12	OD	0.2	1.512	pos	0.012	neg
21347	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgG	EIA	BEP 2000	40564	Mar-12	OD	0.2	1.172	pos	0.005	neg
21412	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgG	EIA	DSX System	40428	Jan-12	OD	0.2	1.02	pos	0.002	neg
31126	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgG	EIA	BEP 2000	40484	Apr-12	OD	0.2	1.142	pos	0	neg
31378	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgG	EIA	BEP 2000	40484	Apr-12	OD	0.2	1.186	pos	0.003	neg
89101	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgG	EIA	BEP III	40598	Jun-12	OD	0.2	1.203	pos	0.001	neg
91119	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgG	EIA	Triturus	40598	Jun-12	OD	0.2	1.09	pos	0	neg
31369	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgG	EIA	BEP III	40484	Apr-12	titre	530	22000	pos	<230	neg
21229	Trinity Biotech	Captia Herpes Group IgG	ELISA	-	531	Jul-12	S/CO	1.1	3.74	pos	0.22	neg
21398	Trinity Biotech	Captia Herpes Group IgG	ELISA	-	531	Jul-12	S/CO	1.1	3.18	pos	0.184	neg
89148	Trinity Biotech	Captia Herpes Group IgG	ELISA	-	530	Feb-12	S/CO	1.1	3.83	pos	0.23	neg

Survey V4:2011:4C & 4D Herpes Simplex Virus type 1 IgG

Part	Manufacturer	Kit Name	Method	Automation	Lot No.	Expiry Date	Units	Cut Off	Value 4C	Result 4C	Value 4D	Result 4D
21721	Biokit	bioelisa HSV-1 IgG	ELISA	-	A-0111	Nov-11	OD	1	2.4	pos	0.27	neg
21624	BION	HSV IFA	IFA	N/A	HS1-0932	Jun-13	titre	320	>320	pos	<320	neg
21092	BioRad	HSV1 IgG	Multiplex	BioPlex 2200	L104994	Apr-12	S/CO	1.1	5.2	pos	<0.2	neg
41302	BioRad	HSV1 IgG	Multiplex	BioPlex 2200	104994	Apr-12	AI	1.1	5.7	pos	<0.20	neg
89045	BioRad	Platelia HSV 1 IgG	EIA	Evolis	IC0015	Sep-12	S/CO	1.1	2.66	pos	0.29	neg
21439	DiaSorin	Liaison HSV-1 IgG	ChLIA	Liaison	126497A	Dec-11	S/CO	0.9	14.3	pos	2.5	pos
89061	DiaSorin	Liaison HSV-1 IgG	ChLIA	Liaison	126797	Jan-12	S/CO	1.2	19.2	pos	1.9	pos
89255	DiaSorin	Liaison HSV-1 IgG	ChLIA	Liaison	126497	Dec-11	S/CO	0.9	17	pos	210	pos
29033	Diesse Diagnostica	Chorus HSV-1 Screen	EIA	Chorus	712	Feb-12	S/CO	1.2	>20	pos	0.3	neg
31234	Euroimmun	Anti-HSV 1 IgG	ELISA	Quantalyser	E110712AF	Jul-12	S/CO	1.1	0.11	neg	3.35	pos
59006	Euroimmun	Anti-HSV 1 IgG	ELISA	-	E110712AF	Jul-12	S/CO	1.1	4.9	pos	0.1	neg
80021	Euroimmun	Anti-HSV 1 IgG	ELISA	-	E110712AF	Jul-12	N/A	16	192	pos	0.7	neg
89035	Euroimmun	Anti-HSV 1 IgG	ELISA	Euroimmun Analyzer1-2P	E1100304AG	Mar-12	S/CO	1.1	2.79	pos	0.05	neg
89051	Euroimmun	Anti-HSV 1 IgG	ELISA	Euroimmun Analyzer1-2P	E110712AF	Jul-12	S/CO	1.1	3.58	pos	0.05	neg
89075	Euroimmun	Anti-HSV 1 IgG	ELISA	-	E110712AF	Jul-12	S/CO	0.8	0.039	neg	0.074	neg
91267	Euroimmun	Anti-HSV 1 IgG	ELISA	-	E110411AP	Apr-12	S/CO	1.1	3.7	pos	0.01	neg
91317	Euroimmun	Anti-HSV 1 IgG	ELISA	-	E110511AN	May-12	S/CO	1.1	2.91	pos	0.04	neg
61100	Euroimmun	Euroline-WB (IgG)	WB	-	D101209AL	Dec-11	N/A	n/a	n/a	pos	n/a	neg
89299	Focus	HSV IgG Differential Immunoblot	Immunoblot	N/A	110491	Dec-11	N/A	n/a	n/a	pos	n/a	neg
21375	Focus Diagnostics	HerpeSelect 1 IgG	ELISA	-	110500	Apr-12	S/CO	1	4.75	pos	0.11	neg
21401	Focus Diagnostics	HerpeSelect 1 IgG	ELISA	Triturus	110500	Apr-12	S/CO	1.1	4.89	pos	0.13	neg
21500	Focus Diagnostics	HerpeSelect 1 IgG	ELISA	Evolis	110500	Apr-12	S/CO	1.1	6.68	pos	0.15	neg
31126	Focus Diagnostics	HerpeSelect 1 IgG	ELISA	-	110500	Apr-12	OD	0.195	1.303	pos	0.014	neg
31369	Focus Diagnostics	HerpeSelect 1 IgG	ELISA	BEP III	110500	Apr-12	S/CO	1.1	6.1	pos	0.15	neg
41018	Focus Diagnostics	HerpeSelect 1 IgG	ELISA	Evolis	110500	Apr-12	OD	0.36	1.65	pos	0.051	neg
41133	Focus Diagnostics	HerpeSelect 1 IgG	ELISA	Evolis	110517	Apr-12	S/CO	1.1	6.7	pos	0.1	neg
51077	Focus Diagnostics	HerpeSelect 1 IgG	ELISA	-	110500	Apr-12	S/CO	1.1	5.91	pos	0.11	neg
61253	Focus Diagnostics	HerpeSelect 1 IgG	ELISA	-	110500	Apr-12	S/CO	1.1	5.21	pos	0.03	neg
61455	Focus Diagnostics	HerpeSelect 1 IgG	ELISA	Triturus	110500	Apr-12	S/CO	1.1	8.6	pos	0.25	neg
83667	Focus Diagnostics	HerpeSelect 1 IgG	ELISA	-	112852	Jul-12	S/CO	1	4.443	pos	0.025	neg

Survey V4:2011:4C & 4D Herpes Simplex Virus type 1 IgG

Part	Manufacturer	Kit Name	Method	Automation	Lot No.	Expiry Date	Units	Cut Off	Value 4C	Result 4C	Value 4D	Result 4D
89041	Focus Diagnostics	HerpeSelect 1 IgG	ELISA	-	112280	Jun-12	S/CO	1.1	4.69	pos	0.14	neg
89212	Focus Diagnostics	HerpeSelect 1 IgG	ELISA	Tecan	110517	Apr-12	S/CO	1	5.2	pos	0.11	neg
89278	Focus Diagnostics	HerpeSelect 1 IgG	ELISA	-	112280	Jul-12	S/CO	0.165	0.224	neg	11.53	pos
91119	Focus Diagnostics	HerpeSelect 1 IgG	ELISA	Triturus	110500	Apr-12	S/CO	1.1	4.72	pos	0.48	neg
91487	Focus Diagnostics	HerpeSelect 1 IgG	ELISA	Triturus	110500	Apr-12	S/CO	1.1	5.62	pos	0.08	neg
89106	GBC	HSV-1 IgG EIA	ELISA	-	RN-41796	Apr-12	S/CO	1	1.16	pos	0.26	neg
89130	Genzyme Virotech	HSV-1 (gG1)	ELISA	Eti-Max 3000	116-01	May-12	S/CO	11	22.69	pos	4	neg
21229	In house	-	WB	-	250511	May-12	N/A	n/a	n/a	pos	n/a	neg
89155	NovaTec Immunodiagnostica	HSV 1 IgG	ELISA	FlexTek 2	HSV1G-051	Nov-11	S/CO	11	16	equ	3.63	neg
89129	ROCHE	HSV 1	ECLIA	Elecsys and cobas e analyser	16350001	May-12	S/CO	0.6	7.1	pos	0.041	neg
89058	Roche Diagnostics	HSV-1 IgG Cobas	Electrochemiluminescence immunoassay	cobas e 601	163500-01	May-12	S/CO	1	5.57	pos	0.023	neg
21292	Siemens Healthcare Diagnostics	Novagnost Herpes simplexVirus 1 IgG	EIA	Triturus	HSV1G-054	May-12	S/CO	11.5	11.6	pos	3.78	neg
31221	Siemens Healthcare Diagnostics	Novagnost Herpes simplex Virus 1 IgG	EIA	BEP2000	54	May-12	OD	1.076	1.328	pos	0.361	neg
41183	Siemens Healthcare Diagnostics	Novagnost Herpes simplex Virus 1 IgG	EIA	BEP III	HSV1G-054	May-12	U	11.5	14.6	pos	4.7	neg
61247	Siemens Healthcare Diagnostics	Novagnost Herpes simplex Virus 1 IgG	EIA	Triturus	HSV1G-054	May-12	S/CO	1.15	0.9	equ	0.35	neg
89148	Trinity Biotech	Captia HSV 1 IgG Type Specific EIA	ELISA	-	534	Nov-11	S/CO	1.1	3.03	pos	0.28	neg
21763	Vital Diagnostics	HSV-1 IgG	ELISA	Triturus	HSV1G11-057-1	Sep-12	U	10	13.1	pos	3.02	neg
29058	Vital Diagnostics	HSV-1 IgG	ELISA	Triturus	HSV1G11-057-1	Sep-12	S/CO	1.1	1.12	pos	0.3	neg
31433	Vital Diagnostics	HSV-1 IgG	ELISA	Triturus	HSV1G-11-054-1	May-12	S/CO	1.1	1.15	pos	0.34	neg

Survey V4:2011:4C & 4D Herpes Simplex Virus type 2 IgG

Part	Manufacturer	Kit Name	Method	Automation	Lot No.	Expiry Date	Units	Cut Off	Value 4C	Result 4C	Value 4D	Result 4D
21721	Biokit	bioelisa HSV-2 IgG	ELISA	-	F-1511	Mar-12	U	0.9	0.25	neg	0.7	neg
21092	BioRad	HSV2 IgG	Multiplex	BioPlex 2200	L104994	Apr-12	AI	1.1	0.6	neg	<0.2	neg
41302	BioRad	HSV2 IgG	Multiplex	BioPlex 2200	104994	Apr-12	AI	1.1	0.6	neg	<0.20	neg
89045	BioRad	Platelia HSV 2 IgG	EIA	Evolis	ID 0016	Oct-12	S/CO	1.1	0.55	neg	0.18	neg
21439	DiaSorin	Liaison HSV-2 IgG	ChLIA	Liaison	76034	Jun-12	S/CO	0.9	0.74	neg	0.5	neg
89061	DiaSorin	Liaison HSV-2 IgG	ChLIA	Liaison	76034	Jun-12	S/CO	1.2	0.8	neg	<0.5	neg
89114	DiaSorin	Liaison HSV-2 IgG	ChLIA	Liaison	76034	Jun-12	S/CO	1.1	0.68	neg	<0.5	neg
89152	DiaSorin	Liaison HSV-2 IgG	ChLIA	Liaison	76034	Jun-12	S/CO	1.1	0.65	neg	0.5	neg
89255	DiaSorin	Liaison HSV-2 IgG	ChLIA	Liaison	76033	Jan-12	S/CO	0.9	1.4	pos	0.5	neg
29033	Diesse Diagnostica	Chorus HSV-2 Screen	EIA	Chorus	697	Dec-11	S/CO	1.2	0.5	neg	0.4	neg
31234	Euroimmun	Anti-HSV 2 IgG	ELISA	Quantalyser	E110725A1	Jul-12	S/CO	1.1	0.11	neg	1.47	pos
59006	Euroimmun	Anti-HSV 2 IgG	ELISA	-	E110526AN	May-12	S/CO	1.1	1.7	pos	0.1	neg
80021	Euroimmun	Anti-HSV 2 IgG	ELISA	-	E110419AT	Apr-12	N/A	16	18	pos	1.1	neg
89035	Euroimmun	Anti-HSV 2 IgG	ELISA	Euroimmun Analyzer1-2P	E101214AW	Dec-11	S/CO	1.1	1.38	pos	0.06	neg
89051	Euroimmun	Anti-HSV 2 IgG	ELISA	Euroimmun Analyzer1-2P	E110526AN	May-12	S/CO	1.1	1.71	pos	0.09	neg
89075	Euroimmun	Anti-HSV 2 IgG	ELISA	-	E110419AT	Apr-12	S/CO	0.8	2.069	pos	0.053	neg
91267	Euroimmun	Anti-HSV 2 IgG	ELISA	-	E110419AT	Apr-12	S/CO	1.1	0.91	equ	0.02	neg
91317	Euroimmun	Anti-HSV 2 IgG	ELISA	-	E110526AN	May-12	S/CO	1.1	0.8	equ	0.05	neg
21375	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	-	111373	Jul-12	S/CO	1	1.18	pos	0.09	neg
21401	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	Triturus	111373	Jul-12	S/CO	1.1	1.43	pos	0.05	neg
21500	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	Evolis	110503	Apr-12	S/CO	1.1	1.12	pos	0.07	neg
31126	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	-	111373	Jul-12	OD	0.19	0.269	pos	0.009	neg
31369	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	BEP III	111373	Jul-12	S/CO	1.1	2	pos	0.11	neg
41018	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	Evolis	111373	Jul-12	OD	0.347	0.622	pos	0.043	neg
41133	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	Evolis	111373	Jul-12	S/CO	1.1	1.9	pos	0.1	neg
51077	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	-	111373	Jul-12	S/CO	1.1	1.61	pos	0.09	neg
61100	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	-	112279	Aug-12	S/CO	1.1	1.4	pos	0.1	neg
61253	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	-	111373	Jul-12	S/CO	1.1	0.61	neg	0	neg
61455	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	Triturus	112279	Jul-12	S/CO	1.1	1.38	pos	0.11	neg
83667	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	-	113145	Aug-12	S/CO	1	0.917	equ	0.096	neg
89041	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	-	111287	Jun-12	S/CO	1.1	1.24	pos	0.1	neg
89212	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	Tecan	111287	Jun-12	S/CO	1	0.87	neg	0.05	neg
89236	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	-	111287	Jun-12	S/CO	1.1	1.149	pos	0.164	neg

Survey V4:2011:4C & 4D Herpes Simplex Virus type 2 IgG

Part	Manufacturer	Kit Name	Method	Automation	Lot No.	Expiry Date	Units	Cut Off	Value 4C	Result 4C	Value 4D	Result 4D
89248	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	-	102799	Nov-11	S/CO	1	1.317	pos	0.263	neg
89278	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	-	111720	Jul-12	S/CO	0.404	0.069	neg	0.173	neg
91119	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	Triturus	10361	Jan-12	S/CO	1.1	1.31	pos	0.6	neg
91487	Focus Diagnostics	HerpeSelect 2 IgG	ELISA	Triturus	103061	Jan-12	S/CO	1.1	1.21	pos	0.04	neg
89299	Focus Diagnostics	HSV IgG Diff Immunoblot	IBA	-	110491	Dec-11	N/A	n/a	n/a	equ	n/a	neg
89106	GBC	HSV-2 IgG EIA	ELISA	-	RN-42198	Aug-12	S/CO	1	1.2	pos	0.73	neg
89130	Genzyme Virotech	HSV-2 (gG2)	ELISA	Eti-Max 3000	121-02	Feb-12	S/CO	11	4.25	neg	0.38	neg
89058	Human	HSV 2 IgG	ELISA	Elisys Uno	11002	Oct-12	S/CO	1.15	2.878	pos	0.162	neg
21229	In house	-	WB	-	130911	Sep-12	N/A	n/a	n/a	pos	n/a	neg
89300	Kalon Biological	Herpes Simplex Type 2 IgG	ELISA	-	K40-126	Mar-12	OD	1.346	0.711	neg	0.479	neg
89107	NovaTec Immunodiagnostica	HSV Type 2 recombinant gG1	ELISA	-	HSV2G 050	Nov-11	OD	0.66	1.653	pos	0.505	neg
21624	Ridascreen	HSV IgG - 2	EIA	-	11180	Feb-12	S/CO	16	7	neg	2	neg
89129	ROCHE	HSV 2	ECLIA	Elecsys and cobas e analyser	16369401	Jun-12	S/CO	0.51	2.42	pos	0.098	neg
21292	Siemens Healthcare Diagnostics	Novagnost Herpes simplex Virus 2 IgG	EIA	Triturus	HSV2G-054	Aug-12	S/CO	11.5	25	pos	4.61	neg
31221	Siemens Healthcare Diagnostics	Novagnost Herpes simplex Virus 2 IgG	EIA	BEP2000	54	Aug-12	OD	0.876	1.746	pos	0.419	neg
41183	Siemens Healthcare Diagnostics	Novagnost Herpes simplex Virus 2 IgG	EIA	BEP III	HSV2G-054	Aug-12	U	11.5	27.7	pos	6.1	neg
61247	Siemens Healthcare Diagnostics	Novagnost Herpes simplex Virus 2 IgG	EIA	Triturus	HSV2G-054	Aug-12	S/CO	1.15	1.16	pos	0.5	neg
89148	Trinity Biotech	Captia HSV 2 IgG Type Specific EIA	ELISA	-	547	Dec-12	S/CO	1.1	0.78	neg	0.14	neg
21763	Vital Diagnostics	HSV-2 IgG	ELISA	Triturus	HSV2G11-054-1	Aug-12	U	10	31	pos	6.5	neg
29058	Vital Diagnostics	HSV-2 IgG	ELISA	Triturus	HSV2G11-054-1	Aug-12	S/CO	1.1	2.6	pos	0.6	neg
31433	Vital Diagnostics	HSV-2 IgG	ELISA	Triturus	HSV2G-11-054-1	Oct-12	S/CO	1.1	3.14	pos	0.72	neg

Survey V4:2011:4C & 4D Herpes Simplex Virus 1&2 IgM

Part	Manufacturer	Kit Name	Method	Automation	Lot No.	Expiry Date	Units	Cut Off	Value 4C	Result 4C	Value 4D	Result 4D
89144	Adaltis Italia	EIAgen HSV 1 & 2 IgM	EIA	-	10	Oct-12	S/CO	1.2	0.291	neg	0.196	neg
21721	Biokit	bioelisa HSV IgM	ELISA	-	A-1811	Jan-12	OD	1	0.5	neg	0.2	neg
59006	Biokit	bioelisa HSV IgM	ELISA	-	A-1811	Jan-12	S/CO	1	0.43	neg	0.5	neg
89061	BioRad	Platelia HSV (1+2) M	EIA	-	210-B	Feb-12	S/CO	1.5	<0.8	neg	<0.8	neg
89152	DiaSorin	Liaison HSV 1/2 IgM	ChLIA	Liaison	77046	Apr-12	S/CO	1.1	0.5	neg	0.5	neg
89255	DiaSorin	Liaison HSV 1/2 IgM	ChLIA	Liaison	77044	Jan-12	S/CO	0.9	0.5	neg	0.5	neg
21375	Diesse Diagnostica	Chorus HSV 1+2 IgM	EIA	Chorus	702	Jan-12	S/CO	1.1	0.2	neg	0.1	neg
29033	Diesse Diagnostica	Chorus HSV 1+2 IgM	EIA	Chorus	702	Jan-12	S/CO	1.1	0.3	neg	0.1	neg
89129	Diesse Diagnostica	HSV 1+2 IgM	EIA	CHORUS	703	Jan-12	S/CO	0.9	0.1	neg	0.1	neg
31234	Euroimmun	Anti-HSV 1/2 IgM	ELISA	Quantalyser	E110505BB	May-12	S/CO	1.1	0.04	neg	0.05	neg
31008	Genzyme Virotech	HSV Screen	ELISA	-	124-01	Jan-12	S/CO	1.1	0.447	neg	0.071	neg
83667	Genzyme Virotech	HSV Screen	ELISA	-	125-01	Oct-12	S/CO	1	0.565	neg	0.285	neg
89019	Genzyme Virotech	HSV Screen	ELISA	-	125-01	Oct-12	OD	0.465	0.338	neg	0.326	neg
89125	Genzyme Virotech	HSV Screen	ELISA	-	125-01	Oct-12	S/CO	1.1	0.329	neg	0.11	neg
89058	Human	HSV IgM	ELISA	-	10004	Feb-12	S/CO	1.15	0.402	neg	0.204	neg
89012	IBL	Herpes Simplex Virus 1-2 IgM	ELISA	-	HSVM-047	May-12	OD	0.408	0.172	neg	0.105	neg
89036	IBL	Herpes Simplex Virus 1-2 IgM	ELISA	-	HSVM-049	Aug-12	OD	0.367	0.123	neg	0.067	neg
61253	In house	HSV IgM	IFA	-	NA	NA	N/A	N/A		not tested	N/A	neg
89046	Meridian Bioscience	Merifluor HSV IgM	IFA	-	HS150 B115	Apr-12	titre	10	<10	neg	<10	neg
89299	SavyonDiagnostics	Sero HSV	ELISA	-	152-L0992700	Nov-11	OD	0.274	0.167	neg	0.071	neg
21229	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgM	EIA	BEP 2000	40485	Mar-12	OD	0.2	0.02	neg	0.01	neg
21267	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgM	EIA	Evolis	40485	Mar-12	OD	0.2		not tested	0	neg
21292	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgM	EIA	Triturus	40485	Mar-12	OD	0.2	0.01	neg	0	neg
21347	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgM	EIA	BEP 2000	40485	Mar-12	OD	0.2	0.02	neg	0.007	neg
21412	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgM	EIA	DSX System	40308	Jan-12	OD	0.2	0.01	neg	0.003	neg
31126	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgM	EIA	BEP 2000	40485	Mar-12	OD	0.2	0.004	neg	0.003	neg
31221	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgM	EIA	BEP 2000	40708	Jun-12	OD	0.2	0.017	neg	0.004	neg

Survey V4:2011:4C & 4D Herpes Simplex Virus 1&2 IgM

Part	Manufacturer	Kit Name	Method	Automation	Lot No.	Expiry Date	Units	Cut Off	Value 4C	Result 4C	Value 4D	Result 4D
31369	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgM	EIA	BEP III	40485	Mar-12	OD	0.2	0.014	neg	0.005	neg
41183	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgM	EIA	BEP III	40485	Mar-12	OD	0.2	0.013	neg	0.004	neg
51077	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgM	EIA	-	40485	Mar-12	S/CO	0.2	0.016	neg	0.006	neg
89101	Siemens Healthcare Diagnostics	Enzygnost Anti-HSV IgM	EIA	BEP III	40485	Mar-12	OD	0.2	0	neg	0.002	neg
89041	Trinity Biotech	Captia Herpes Simplex Combined IgM	ELISA	-	2326660-020	Feb-12	S/CO	1.1	0.37	neg	0.26	neg
89148	Trinity Biotech	Captia Herpes Simplex Combined IgM	ELISA	-	20	Feb-12	S/CO	1.1	0.26	neg	0.21	neg
89227	Trinity Biotech	Captia Herpes Simplex Combined IgM	ELISA	-	2326660-020	Feb-12	S/CO	0.49	0.33	neg	0.37	neg
89278	Trinity Biotech	Captia Herpes Simplex Combined IgM	ELISA	-	2326660-020	Jan-12	S/CO	0.739	0.79	neg	0.467	neg
21763	Vital Diagnostics	HSV 1 + 2 IgM	ELISA	Triturus	HSVM11-049-1	Aug-12	NTU	10	3.05	neg	1.3	neg
29058	Vital Diagnostics	HSV 1 + 2 IgM	ELISA	Triturus	HSVM11-049-1	Aug-12	S/CO	1.1	0.2	neg	0.1	neg

Survey V4:2011:4C &4D Herpes Simplex Virus type 1 IgM

Part	Manufacturer	Kit Name	Method	Automation	Lot No.	Expiry Date	Units	Cut Off	Value 4C	Result 4C	Value 4D	Result 4D
21624	BION	HSV IFA	IFA	N/A	HS1-0932	Jun-13	titre	10	<10	neg	<10	neg
89051	Euroimmun	Anti-HSV 1 IgM	ELISA	Euroimmun Analyzer1-2P	E110725AH	Jul-12	S/CO	1.1	0.17	neg	0.06	neg
21229	EUROIMMUN	HSV-1 and -2 Immunoblot	Immunoblot	manual	D110916AD	Mar-13	N/A	N/A	N/A	neg	N/A	neg
89106	GBC	HSV-1 IgM EIA	ELISA	-	RN-40942	Mar-12	S/CO	1	0.3	neg	0.15	neg
89130	Genzyme Virotech	HSV-1 (gG1)	ELISA	Eti-Max 3000	116-01	May-12	S/CO	11	0.214	neg	0.86	neg
89155	NovaTec Immunodiagnostica	HSV 1 IgM	ELISA	FlexTek 2	HSV1M-052	Jan-12	S/CO	11	3	neg	1.09	neg
89078	NovaTec Immunodiagnostica	NovaLisa (HSV1) IgM	ELISA	-	HSV1M 052	Jan-12	OD	0.431	0.103	neg	0.036	neg
89148	Trinity Biotech	Captia HSV 1 IgM	ELISA	-	23	Sep-12	S/CO	1.1	0.19	neg	0.14	neg

Survey V4:2011:4C & 4D Herpes Simplex Virus type 2 IgM

Part	Manufacturer	Kit Name	Method	Automation	Lot No.	Expiry Date	Units	Cut Off	Value 4C	Result 4C	Value 4D	Result 4D
21624	BION	HSV IFA	IFA	N/A	HS2-0926	Mar-13	titre	10	<10	neg	<10	neg
89051	Euroimmun	Anti-HSV 2 IgM	ELISA	Euroimmun Analyzer1-2P	E110510BD	May-12	S/CO	1.1	0.21	neg	0.06	neg
21229	EUROIMMUN	Immunoblot	Immunoblot	Manual	D110916AD	Mar-13	N/A	N/A	N/A	neg	N/A	neg
89106	GBC	HSV-2 IgM EIA	ELISA	-	RN-41084	Apr-12	S/CO	1	0.51	neg	0.42	neg
89130	Genzyme Virotech	HSV-2 (gG2)	ELISA	Eti-Max 3000	121-02	Feb-12	S/CO	11	0.04	neg	0.39	neg
89078	NovaTec Immunodiagnostica	HSV 2 IgM	ELISA	-	HSV2M- 053	Mar-12	OD	0.315	0.007	neg	0.001	neg
89107	NovaTec Immunodiagnostica	HSV 2 IgM	ELISA	-	HSV2M- 049	Nov-11	OD	0.71	0.135	neg	0.109	neg
89148	Trinity Biotech	Captia HSV-2 IgM	ELISA	-	24	Feb-13	S/CO	1.1	0.2	neg	0.12	neg

Survey V4:2011:4C & 4D Herpes Simplex Virus CFT

Part	Manufacturer	Kit Name	Method	Lot No.	Expiry Date	Units	Cut Off	Value 4C	Result 4C	Value 4D	Result 4D
21375	Siemens Healthcare Diagnostics	HSV Antigen	CFT	SMA.AH	Dec-20	titre	32	>256	AC	<8	neg
21624	Siemens Healthcare Diagnostics	HSV Antigen	CFT	SEZ.DR	May-19	titre	16	16	equ	<4	neg
89046	Virion	HSV Antigen	CFT	972030.03.5	Mar-13	titre	8	32	pos	<8	neg