

EQA round: AIM11/25 - Autoimmunity 1

Deadline: 14.3.2025

Setup: groups - R (manufacturer of kit)

AV = assigned value

N_{tot} = total number of the resultsN_{eva} = number of the results assessed

CVP = consensus of all participants

N_{rel} = relative number of the resultsN_{suc} = number of successful results

>>> ... expected result

S_{rel} = relative success

> ... acceptable result

± ... result not assessed

Test Sample Group	Frequency of the results					Success		
	AV	N _{tot}	N _{rel} [%]	Result	N _{eva}	N _{suc}	S _{rel} [%]	
Set 1								
(560) ANA screening (antibodies against cell nucleus) - prove		81			81	81	100	
Sample A1		81			81	81	100	
(14) Bio-Rad	CVP >>>	1	1,2	Positive				
(73) Snibe	CVP >>>	1	1,2	Positive				
(87) Euroimmun	CVP >>>	49	60	Positive				
(103) Immunoconcepts	CVP >>>	2	2,5	Positive				
(115) BioSystems	CVP >>>	5	6,2	Positive				
(135) OrgenTec	CVP >>>	1	1,2	Positive				
(148) Aesku.lab Diagnostika	CVP >>>	10	12	Positive				
(166) Thermo Fisher	CVP >>>	1	1,2	Positive				
(211) INOVA Diagnostics	CVP >>>	11	14	Positive				
Sample B1		81			81	81	100	
(14) Bio-Rad	CVP >>>	1	1,2	Negative				
(73) Snibe	CVP >>>	1	1,2	Negative				
(87) Euroimmun	CVP >>>	49	60	Negative				
(103) Immunoconcepts	CVP >>>	2	2,5	Negative				
(115) BioSystems	CVP >>>	5	6,2	Negative				
(135) OrgenTec	CVP >>>	1	1,2	Negative				
(148) Aesku.lab Diagnostika	CVP >>>	10	12	Negative				
(166) Thermo Fisher	CVP >>>	1	1,2	Negative				
(211) INOVA Diagnostics	CVP >>>	11	14	Negative				
(572) ANA screening (antibodies against cell nucleus) - semi-quantity		71			0			
Sample A1		71			0			
(87) Euroimmun	±	1	1,4	titre 40				
	±	2	2,8	titre 80				
	±	1	1,4	titre 160				
	±	13	18	titre 320				
	±	18	25	titre 640				
	±	8	11	titre 1280				
	±	3	4,2	titre 2560				
(103) Immunoconcepts	±	2	2,8	titre 320				
(115) BioSystems	±	1	1,4	titre 40				
	±	1	1,4	titre 160				
	±	1	1,4	titre 640				
	±	1	1,4	titre 1280				
(148) Aesku.lab Diagnostika	±	4	5,6	titre 320				
	±	2	2,8	titre 640				
	±	2	2,8	titre 1280				
(211) INOVA Diagnostics	±	7	9,9	titre 320				
	±	2	2,8	titre 640				
	±	1	1,4	titre 1280				
	±	1	1,4	titre 2560				
Sample B1		71			0			
(87) Euroimmun	±	1	1,4	Not specified				
	±	37	52	titre 0 (not measurable)				
	±	2	2,8	titre 40				
	±	5	7	titre 80				
	±	1	1,4	titre 2560				
(103) Immunoconcepts	±	1	1,4	titre 40				
	±	1	1,4	titre 80				
(115) BioSystems	±	2	2,8	titre 0 (not measurable)				
	±	2	2,8	titre 40				
(148) Aesku.lab Diagnostika	±	6	8,5	titre 0 (not measurable)				
	±	2	2,8	titre 80				
(211) INOVA Diagnostics	±	11	15	titre 0 (not measurable)				
(561) ANA - type of fluorescence - nucleus		74			74	70	95	
Sample A1		74			74	73	99	
(0) not specified	CVP >>>	73	99	Fine or coarse speckled or nuclear matrix (AC-4/AC-5)				
		1	1,4	Fine or coarse speckled or nuclear matrix (AC-4/AC-5); DFS 70 (AC-2)				

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	AV	N _{tot}	N _{rel} [%]	Result	N _{eva}	N _{suc}	S _{rel} [%]	
Sample B1		74				74	71	96
(0) not specified		3	4,1	Not specified				
	CVP >>>	71	96	No fluorescence (AC-0)				
(563) ANA screening (antibodies against cytoplasm) - prove		72				72	71	99
Sample A1		72				72	71	99
(87) Euroimmun	CVP >>>	45	63	Negative				
		1	1,4	Positive				
(103) Immunoconcepts	CVP >>>	2	2,8	Negative				
(115) BioSystems	CVP >>>	5	6,9	Negative				
(148) Aesku.lab Diagnostika	CVP >>>	8	11	Negative				
(211) INOVA Diagnostics	CVP >>>	11	15	Negative				
Sample B1		72				72	72	100
(87) Euroimmun	CVP >>>	46	64	Negative				
(103) Immunoconcepts	CVP >>>	2	2,8	Negative				
(115) BioSystems	CVP >>>	5	6,9	Negative				
(148) Aesku.lab Diagnostika	CVP >>>	8	11	Negative				
(211) INOVA Diagnostics	CVP >>>	11	15	Negative				
(573) ANA screening (antibodies against cytoplasm) - semi-quantity		68				0		
Sample A1		68				0		
(0) not specified	±	1	1,5	titre 40				
(87) Euroimmun	±	34	50	titre 0 (not measurable)				
	±	1	1,5	titre 40				
	±	5	7,4	titre 80				
	±	1	1,5	titre 640				
	±	1	1,5	titre 2560				
(103) Immunoconcepts	±	1	1,5	titre 40				
	±	1	1,5	titre 80				
(115) BioSystems	±	2	2,9	titre 0 (not measurable)				
	±	2	2,9	titre 40				
(148) Aesku.lab Diagnostika	±	6	8,8	titre 0 (not measurable)				
	±	2	2,9	titre 80				
(211) INOVA Diagnostics	±	11	16	titre 0 (not measurable)				
Sample B1		68				0		
(0) not specified	±	1	1,5	titre 40				
(87) Euroimmun	±	35	51	titre 0 (not measurable)				
	±	1	1,5	titre 40				
	±	5	7,4	titre 80				
	±	1	1,5	titre 2560				
(103) Immunoconcepts	±	1	1,5	titre 40				
	±	1	1,5	titre 80				
(115) BioSystems	±	2	2,9	titre 0 (not measurable)				
	±	2	2,9	titre 40				
(148) Aesku.lab Diagnostika	±	6	8,8	titre 0 (not measurable)				
	±	2	2,9	titre 80				
(211) INOVA Diagnostics	±	11	16	titre 0 (not measurable)				
(564) ANA - type of fluorescence - cytoplasm		69				69	68	99
Sample A1		69				69	68	99
(0) not specified	CVP >>>	68	99	No fluorescence (AC-0)				
		1	1,4	Dense or fine speckled cytoplasm (AC-19/AC-20)				
Sample B1		69				69	69	100
(0) not specified	CVP >>>	69	100	No fluorescence (AC-0)				
Set 2								
(585) anti-centromere		75				75	75	100
Sample A2		75				75	75	100
(32) Human	CVP >>>	1	1,3	Negative				
(87) Euroimmun	CVP >>>	39	52	Negative				
(98) Fujirebio	CVP >>>	1	1,3	Negative				
(135) OrgenTec	CVP >>>	4	5,3	Negative				
(140) TestLine	CVP >>>	15	20	Negative				
(148) Aesku.lab Diagnostika	CVP >>>	2	2,7	Negative				
(166) Thermo Fisher	CVP >>>	7	9,3	Negative				
(191) D-tek	CVP >>>	2	2,7	Negative				
(211) INOVA Diagnostics	CVP >>>	2	2,7	Negative				
(999) another manufacturer	CVP >>>	2	2,7	Negative				
Sample B2		75				75	75	100
(32) Human	CVP >>>	1	1,3	Negative				

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Test Sample Group	AV	N _{tot}	Frequency of the results		Success		
			N _{rel} [%]	Result	N _{eva}	N _{suc}	S _{rel} [%]
(87) Euroimmun	CVP >>>	39	52	Negative			
(98) Fujirebio	CVP >>>	1	1,3	Negative			
(135) OrgenTec	CVP >>>	4	5,3	Negative			
(140) TestLine	CVP >>>	15	20	Negative			
(148) Aesku.lab Diagnostika	CVP >>>	2	2,7	Negative			
(166) Thermo Fisher	CVP >>>	7	9,3	Negative			
(191) D-tek	CVP >>>	2	2,7	Negative			
(211) INOVA Diagnostics	CVP >>>	2	2,7	Negative			
(999) another manufacturer	CVP >>>	2	2,7	Negative			
(584) anti-ENA, antigen Jo-1		78			78	77	99
Sample A2		78			78	77	99
(32) Human	CVP >>>	1	1,3	Negative			
(34) Sebia	CVP >>>	1	1,3	Negative			
(38) Werfen (IL)	CVP >>>	1	1,3	Negative			
		1	1,3	Inconclusive result (borderline)			
(87) Euroimmun	CVP >>>	35	45	Negative			
(98) Fujirebio	CVP >>>	1	1,3	Negative			
(135) OrgenTec	CVP >>>	4	5,1	Negative			
(140) TestLine	CVP >>>	15	19	Negative			
(148) Aesku.lab Diagnostika	CVP >>>	4	5,1	Negative			
(166) Thermo Fisher	CVP >>>	9	12	Negative			
(191) D-tek	CVP >>>	2	2,6	Negative			
(211) INOVA Diagnostics	CVP >>>	2	2,6	Negative			
(999) another manufacturer	CVP >>>	2	2,6	Negative			
Sample B2		78			78	78	100
(32) Human	CVP >>>	1	1,3	Negative			
(34) Sebia	CVP >>>	1	1,3	Negative			
(38) Werfen (IL)	CVP >>>	2	2,6	Negative			
(87) Euroimmun	CVP >>>	35	45	Negative			
(98) Fujirebio	CVP >>>	1	1,3	Negative			
(135) OrgenTec	CVP >>>	4	5,1	Negative			
(140) TestLine	CVP >>>	15	19	Negative			
(148) Aesku.lab Diagnostika	CVP >>>	4	5,1	Negative			
(166) Thermo Fisher	CVP >>>	9	12	Negative			
(191) D-tek	CVP >>>	2	2,6	Negative			
(211) INOVA Diagnostics	CVP >>>	2	2,6	Negative			
(999) another manufacturer	CVP >>>	2	2,6	Negative			
(583) anti-ENA, antigen RNP		78			78	67	86
Sample A2		78			78	68	87
(32) Human	CVP >>>	1	1,3	Positive			
(34) Sebia	CVP >>>	1	1,3	Positive			
(38) Werfen (IL)	CVP >>>	2	2,6	Positive			
(87) Euroimmun		1	1,3	Negative			
		1	1,3	Inconclusive result (borderline)			
	CVP >>>	34	44	Positive			
(98) Fujirebio	CVP >>>	1	1,3	Positive			
(135) OrgenTec	CVP >>>	4	5,1	Positive			
(140) TestLine		4	5,1	Negative			
	CVP >>>	11	14	Positive			
(148) Aesku.lab Diagnostika		2	2,6	Negative			
	CVP >>>	1	1,3	Positive			
(166) Thermo Fisher		1	1,3	Negative			
	CVP >>>	8	10	Positive			
(191) D-tek	CVP >>>	2	2,6	Positive			
(211) INOVA Diagnostics	CVP >>>	2	2,6	Positive			
(999) another manufacturer		1	1,3	Negative			
	CVP >>>	1	1,3	Positive			
Sample B2		78			78	77	99
(32) Human	CVP >>>	1	1,3	Negative			
(34) Sebia	CVP >>>	1	1,3	Negative			
(38) Werfen (IL)	CVP >>>	2	2,6	Negative			
(87) Euroimmun	CVP >>>	36	46	Negative			
(98) Fujirebio	CVP >>>	1	1,3	Negative			
(135) OrgenTec	CVP >>>	4	5,1	Negative			
(140) TestLine	CVP >>>	14	18	Negative			
		1	1,3	Positive			
(148) Aesku.lab Diagnostika	CVP >>>	3	3,8	Negative			
(166) Thermo Fisher	CVP >>>	9	12	Negative			
(191) D-tek	CVP >>>	2	2,6	Negative			

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			N _{rel} [%]	Result	N _{eva}	N _{suc}	S _{rel} [%]	
(211) INOVA Diagnostics	CVP >>>	2	2,6	Negative				
(999) another manufacturer	CVP >>>	2	2,6	Negative				
(582) anti-ENA, antigen Scl-70		78			78	78	100	
Sample A2		78			78	78	100	
(32) Human	CVP >>>	1	1,3	Negative				
(34) Sebia	CVP >>>	1	1,3	Negative				
(38) Werfen (IL)	CVP >>>	2	2,6	Negative				
(87) Euroimmun	CVP >>>	36	46	Negative				
(98) Fujirebio	CVP >>>	1	1,3	Negative				
(135) OrgenTec	CVP >>>	4	5,1	Negative				
(140) TestLine	CVP >>>	15	19	Negative				
(148) Aesku.lab Diagnostika	CVP >>>	4	5,1	Negative				
(166) Thermo Fisher	CVP >>>	9	12	Negative				
(191) D-tek	CVP >>>	1	1,3	Negative				
(211) INOVA Diagnostics	CVP >>>	2	2,6	Negative				
(999) another manufacturer	CVP >>>	2	2,6	Negative				
Sample B2		78			78	78	100	
(32) Human	CVP >>>	1	1,3	Negative				
(34) Sebia	CVP >>>	1	1,3	Negative				
(38) Werfen (IL)	CVP >>>	2	2,6	Negative				
(87) Euroimmun	CVP >>>	36	46	Negative				
(98) Fujirebio	CVP >>>	1	1,3	Negative				
(135) OrgenTec	CVP >>>	4	5,1	Negative				
(140) TestLine	CVP >>>	15	19	Negative				
(148) Aesku.lab Diagnostika	CVP >>>	4	5,1	Negative				
(166) Thermo Fisher	CVP >>>	9	12	Negative				
(191) D-tek	CVP >>>	1	1,3	Negative				
(211) INOVA Diagnostics	CVP >>>	2	2,6	Negative				
(999) another manufacturer	CVP >>>	2	2,6	Negative				
(580) anti-ENA, antigen SS-A/Ro-60		78			78	78	100	
Sample A2		78			78	78	100	
(32) Human	CVP >>>	1	1,3	Positive				
(34) Sebia	CVP >>>	1	1,3	Positive				
(38) Werfen (IL)	CVP >>>	2	2,6	Positive				
(87) Euroimmun	CVP >>>	36	46	Positive				
(98) Fujirebio	CVP >>>	1	1,3	Positive				
(135) OrgenTec	CVP >>>	4	5,1	Positive				
(140) TestLine	CVP >>>	15	19	Positive				
(148) Aesku.lab Diagnostika	CVP >>>	4	5,1	Positive				
(166) Thermo Fisher	CVP >>>	9	12	Positive				
(191) D-tek	CVP >>>	1	1,3	Positive				
(211) INOVA Diagnostics	CVP >>>	2	2,6	Positive				
(999) another manufacturer	CVP >>>	2	2,6	Positive				
Sample B2		78			78	78	100	
(32) Human	CVP >>>	1	1,3	Negative				
(34) Sebia	CVP >>>	1	1,3	Negative				
(38) Werfen (IL)	CVP >>>	2	2,6	Negative				
(87) Euroimmun	CVP >>>	36	46	Negative				
(98) Fujirebio	CVP >>>	1	1,3	Negative				
(135) OrgenTec	CVP >>>	4	5,1	Negative				
(140) TestLine	CVP >>>	15	19	Negative				
(148) Aesku.lab Diagnostika	CVP >>>	4	5,1	Negative				
(166) Thermo Fisher	CVP >>>	9	12	Negative				
(191) D-tek	CVP >>>	1	1,3	Negative				
(211) INOVA Diagnostics	CVP >>>	2	2,6	Negative				
(999) another manufacturer	CVP >>>	2	2,6	Negative				
(581) anti-ENA, antigen SS-B/La		78			78	78	100	
Sample A2		78			78	78	100	
(32) Human	CVP >>>	1	1,3	Positive				
(34) Sebia	CVP >>>	1	1,3	Positive				
(38) Werfen (IL)	CVP >>>	2	2,6	Positive				
(87) Euroimmun	CVP >>>	36	46	Positive				
(98) Fujirebio	CVP >>>	1	1,3	Positive				
(135) OrgenTec	CVP >>>	4	5,1	Positive				
(140) TestLine	CVP >>>	15	19	Positive				
(148) Aesku.lab Diagnostika	CVP >>>	4	5,1	Positive				
(166) Thermo Fisher	CVP >>>	9	12	Positive				
(191) D-tek	CVP >>>	1	1,3	Positive				
(211) INOVA Diagnostics	CVP >>>	2	2,6	Positive				

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			N _{rel} [%]	Result	N _{eva}	N _{suc}	S _{rel} [%]
(999) another manufacturer	CVP >>>	2	2,6	Positive			
Sample B2		78			78	78	100
(32) Human	CVP >>>	1	1,3	Negative			
(34) Sebia	CVP >>>	1	1,3	Negative			
(38) Werfen (IL)	CVP >>>	2	2,6	Negative			
(87) Euroimmun	CVP >>>	36	46	Negative			
(98) Fujirebio	CVP >>>	1	1,3	Negative			
(135) OrgenTec	CVP >>>	4	5,1	Negative			
(140) TestLine	CVP >>>	15	19	Negative			
(148) Aesku.lab Diagnostika	CVP >>>	4	5,1	Negative			
(166) Thermo Fisher	CVP >>>	9	12	Negative			
(191) D-tek	CVP >>>	1	1,3	Negative			
(211) INOVA Diagnostics	CVP >>>	2	2,6	Negative			
(999) another manufacturer	CVP >>>	2	2,6	Negative			
Set 3							
(588) anti-dsDNA immunofluorescence - prove		56			56	54	96
Sample A3		56			56	55	98
(87) Euroimmun	CVP >>>	39	70	Negative			
		1	1,8	Positive			
(115) BioSystems	CVP >>>	3	5,4	Negative			
(148) Aesku.lab Diagnostika	CVP >>>	1	1,8	Negative			
(211) INOVA Diagnostics	CVP >>>	12	21	Negative			
Sample B3		56			56	54	96
(87) Euroimmun		2	3,6	Negative			
	CVP >>>	38	68	Positive			
(115) BioSystems	CVP >>>	3	5,4	Positive			
(148) Aesku.lab Diagnostika	CVP >>>	1	1,8	Positive			
(211) INOVA Diagnostics	CVP >>>	12	21	Positive			
(577) anti-dsDNA immunofluorescence - semi-quantity		52			0		
Sample A3		52			0		
(87) Euroimmun	±	1	1,9	Not specified			
	±	28	54	titre 0 (not measurable)			
	±	5	9,6	titre 10			
	±	1	1,9	titre 2560			
(115) BioSystems	±	3	5,8	titre 0 (not measurable)			
(148) Aesku.lab Diagnostika	±	1	1,9	titre 0 (not measurable)			
(211) INOVA Diagnostics	±	12	23	titre 0 (not measurable)			
	±	1	1,9	titre 10			
Sample B3		52			0		
(87) Euroimmun	±	2	3,8	titre 10			
	±	3	5,8	titre 20			
	±	1	1,9	titre 40			
	±	10	19	titre 80			
	±	6	12	titre 160			
	±	10	19	titre 320			
	±	2	3,8	titre 640			
	±	1	1,9	titre 2560			
(115) BioSystems	±	3	5,8	titre 80			
(148) Aesku.lab Diagnostika	±	1	1,9	titre 40			
(211) INOVA Diagnostics	±	3	5,8	titre 80			
	±	5	9,6	titre 160			
	±	3	5,8	titre 320			
	±	2	3,8	titre 640			
(589) anti-dsDNA other methods		61			61	56	92
Sample A3		61			61	58	95
(34) Sebia	CVP >>>	1	1,6	Negative			
(38) Werfen (IL)	CVP >>>	2	3,3	Negative			
(49) BioVendor	CVP >>>	1	1,6	Negative			
(73) Snibe	CVP >>>	2	3,3	Negative			
(87) Euroimmun	CVP >>>	21	34	Negative			
(135) OrgenTec	CVP >>>	9	15	Negative			
(140) TestLine	CVP >>>	5	8,2	Negative			
(148) Aesku.lab Diagnostika	CVP >>>	4	6,6	Negative			
(166) Thermo Fisher	CVP >>>	8	13	Negative			
(183) Immunodiagnostic Systems	CVP >>>	1	1,6	Negative			
(191) D-tek	CVP >>>	1	1,6	Negative			
(211) INOVA Diagnostics	CVP >>>	2	3,3	Negative			

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			N _{rel} [%]	Result	N _{eva}	N _{suc}	S _{rel} [%]	
		2	3,3	Inconclusive result (borderline)				
		1	1,6	Positive				
(999) another manufacturer	CVP >>>	1	1,6	Negative				
Sample B3		61				61	59	97
(34) Sebia	CVP >>>	1	1,6	Positive				
(38) Werfen (IL)	CVP >>>	2	3,3	Positive				
(49) BioVendor	CVP >>>	1	1,6	Positive				
(73) Snibe	CVP >>>	2	3,3	Positive				
(87) Euroimmun		2	3,3	Negative				
	CVP >>>	19	31	Positive				
(135) OrgenTec	CVP >>>	9	15	Positive				
(140) TestLine	CVP >>>	5	8,2	Positive				
(148) Aesku.lab Diagnostika	CVP >>>	4	6,6	Positive				
(166) Thermo Fisher	CVP >>>	8	13	Positive				
(183) Immunodiagnostic Systems	CVP >>>	1	1,6	Positive				
(191) D-tek	CVP >>>	1	1,6	Positive				
(211) INOVA Diagnostics	CVP >>>	5	8,2	Positive				
(999) another manufacturer	CVP >>>	1	1,6	Positive				
Set 4								
(591) anti-nukleosomes IgG		55				55	55	100
Sample A4		55				55	55	100
(17) Biogema	CVP >>>	2	3,6	Negative				
(87) Euroimmun	CVP >>>	30	55	Negative				
(135) OrgenTec	CVP >>>	17	31	Negative				
(140) TestLine	CVP >>>	2	3,6	Negative				
(148) Aesku.lab Diagnostika	CVP >>>	2	3,6	Negative				
(191) D-tek	CVP >>>	2	3,6	Negative				
Sample B4		55				55	55	100
(17) Biogema	CVP >>>	2	3,6	Positive				
(87) Euroimmun	CVP >>>	30	55	Positive				
(135) OrgenTec	CVP >>>	17	31	Positive				
(140) TestLine	CVP >>>	2	3,6	Positive				
(148) Aesku.lab Diagnostika	CVP >>>	2	3,6	Positive				
(191) D-tek	CVP >>>	2	3,6	Positive				