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THE DREAM OF AN EQA PROVIDER: A HARMONIZED WAY OF COMPLETING EQA FORMS

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Symposium Non-infectious serology 22/11/2019

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IMPORTANCE!!

- Reporting of EQA results
- Correct & complete information
  - -> correct evaluation of results
  - -> traceability of ‘incorrect’ results
  - -> complete kit name & catalogue number
- FORMs are a part of the ISO17043 quality system
- Signature -> confirmation of results by responsible

CHECK BEFORE SUBMITTING!!

Submit scan via e-mail!!

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Indirect Immunofluorescence (IIF)

IIF SUBSTRAAT

		Code fabrikant	Naam kit	Catalogus-nummer *	Lotnummer individuele componenten °
1010	[x] Hep-2 cellen [ ] Hep-2000 cellen [ ] Hep-2010 cellen	102	IIFT: mosaic basic profile 3A	FA-1802-1005	Substraat : .... Conjugaat : ....

3 types of cell lines

- HEp-2
- HEp-2010: higher portion of mitotic cells -> better identification of antibodies against mitosis-specific structures
- HEp-2000: genetically engineered cells -> higher sensitivity to SSA autoantibodies

IIF (cont.)

Which cells where?

	HEp-2	HEp-2010	HEp-2000
Alphadia	x		
DiaSorin	x		
EUROIMMUN	x	x	
Immuno Concepts	x		x
Inova Diagn.	x		
Kallestad	x		
Menarini Diagn.	x		

IIF - technique

TECHNIQUE IFI

Application et incubation de l'échantillon

☐ Manuelle

☐ Automatisée

Dilution de screening: 1/.....

Nom appareil: .....

Firme appareil: .....

Lecture de l'immunofluorescence

☐ Manuelle

☐ Automatisée avec lecture d'un titre final basé sur :

☐ une dilution : 1/..... ☐ série de dilutions

Nom microscope: .....

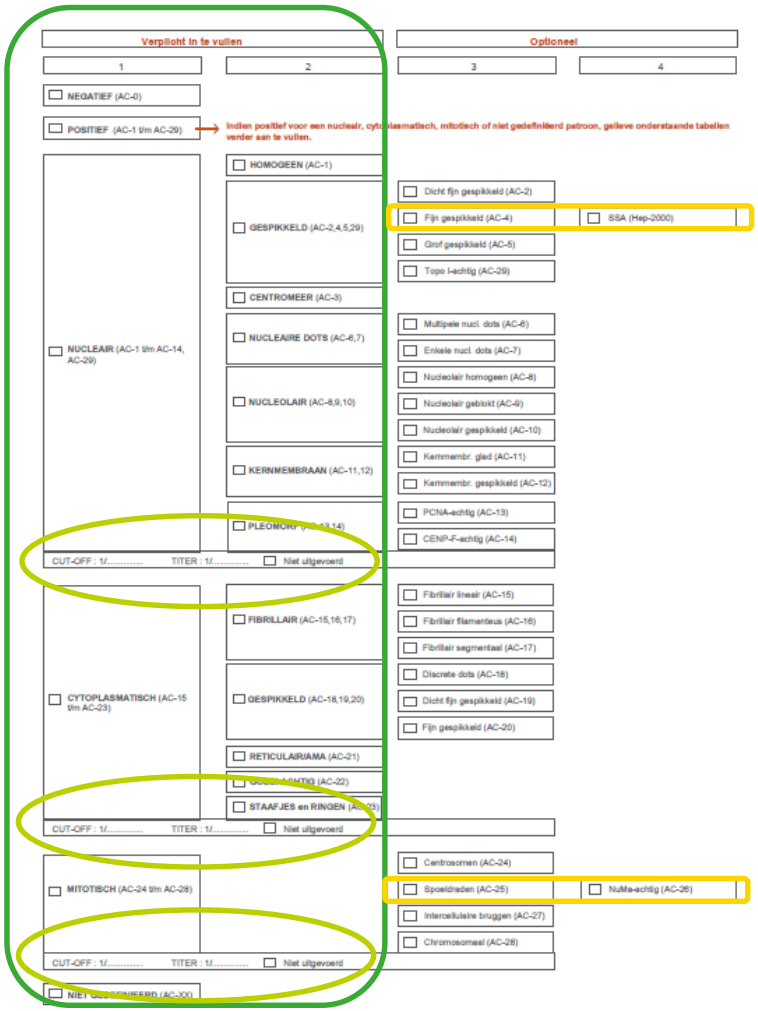
Firme microscope : .....

Est-ce que le résultat de la lecture de l'immuno-fluorescence est corrigé par l'opérateur: ☐ Oui ☐ Non

Info used for:

- Evaluation of manual vs automatic
- Evaluation of one method vs other + within method
- Evolution of technique used

IIF - ANA patterns



Based on:

- ICAP nomenclature

https://www.anapatterns.org/view_pattern.php?pattern=2

- FR/DE: cf. website

  NL: Damoiseaux et al., 2018

- Regular updates

Important:

- Complete at least level 1 and 2
- Complete titer and cut-off

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Anti-dsDNA

		Code Fabricant	Titre/con-centration	Unité	Cut-off	+, - ou +/-
2010	Crithidia luciliae	. . .				
2020	RIA	. . .				
2030	dsDNA ELISA / EIA / FEIA	. . .				
2040	dsDNA dot	. . .				

- FORM will be adapted to report different kits when >1 method is used
- Addition of µ-array
- Sometimes anti-dsDNA analysis is done within anti-ENA kit:

  e.g. AESKU Dot, EUROLine

  -> report it here

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Anti-ENA - screening

3080	ANA / Anti-ENA **SCREENING**				
Methode 1	Code zie p. 6/10	+ , - of +/-	Methode 2	Code zie p. 6/10	+ , - of +/-
	.305.	+SSA + SSB		- - -	
	Naam kit : ENA dot 7			Naam kit :	
	Catalogusnummer : HM042			Catalogusnummer :	

Gelieve in onderstaande tabel, voor elke methode (M1 en M2), de in uw kit aanwezige antigenen aan te kruisen.

	ANA / Anti-ENA Screening					
	Recombinant		Natief		Synthetisch	
	M 1	M 2	M 1	M 2	M 1	M 2
SSA (Ro)						
Ro-52						
Ro-60						
SSB (La)						
Sm						
Sm/RNP						
RNP						
Jo1						
Scl-70						
CENP-B						
CENP-A/B						
Rib-P						

Screening = non specific analysis

- Does not give you which Ab is present
- Positive/negative result

e.g. ANA-8 ELISA - Theradiag
ANA (IgG) screen ELISA - EUROIMMUN
ENA 7 screen QUANTAFlash - Inova Diagn.
EliA CTD screen/EliA Symphony well - Phadia
ENA screen ELISA - Orgentec
ENA screen ELISA - Menarini Diagn.
ANA-8S ELISA - AESKU
EU-8 ENA S ELISA - Launch Diagn.
ENA/ANA screen EIA assay - BIO-RAD

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Anti-ENA - identification

3030	**IDENTIFICATION** : immuno dot / line		
	Code	**Nom du kit**	**N° de catalogue**
Méthode 1	. . .		
Méthode 2	. . .		

3050	**IDENTIFICATION** : ELISA / EIA / FEIA / CLIA		
	Code	**Nom du kit**	**N° de catalogue**
Méthode 1	. . .		
Méthode 2	. . .		

Identification = specific analysis

- Gives you which Ab is present
- Dot/Line = qualitative/quantitative
- ELISA/CLIA/FEIA = quantitative

Gelieve in onderstaande tabel, voor elke methode (M1 en M2), de in uw kit aanwezige antigenen aan te kruiser
Gelieve ook voor elk geanalyseerd antigen, het bekomen resultaat (+, +/-, -) in te vullen.

	IDENTIFICATIE – Methode 1						
	Recombinant	Natief	Synthetisch	Concentratie*	Eenheid	Cut-off	Besluit +, +/-, -
SSA (Ro)							
Ro-52							
Ro-60							
SSB (La)							
Sm							
Sm/RNP							
RNP							
Jo1							
Scl-70							
CENP-B							
CENP-A/B							
Rib-P							
.....							

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Anti-ENA – identification: SSA/Ro60

Company	e.g. kit	SSA = Ro60+Ro52	SSA = Ro60
AESKU	ANA-17 Pro (blot)		x
Alphadia	ENA DOT ANA+DFS70 PROFILE 10 Ag DOT		x
D-Tek	Quantrix + Dot		x
EUROIMMUN	EUROLine		x
IDS	CLIA SSA/Ro CLIA SSA/Ro60	x	x
Inova Diagn.	QUANTALite ENA profile	x	
Menarini Diagn.	Zenit RA SSA/Ro ENA profile AMidot array	x x	x
Mikrogen Diagn.	recomLine ANA/ENA IgG		x
Theradiag	ENA Dot 7 ENALISA	x	x
Phadia/ThermoSc	Elia Ro	x	

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Anti-ENA – identification: SSA/Ro60

Company	e.g. kit	SSA = Ro60+Ro52	SSA = Ro60
AESKU	ANA-17 Pro (blot)		x
Alphadia	ENA DOT ANA+DFS70 PROFILE 10 Ag DOT		x
D-Tek	Quantrix + Dot		x
EUROIMMUN	EUROLine		x
IDS	CLIA SSA/Ro CLIA SSA/Ro60	x	x
Inova Diagn.	QUANTALite ENA profile	x	
Menarini Diagn.	Zenit RA SSA/Ro ENA profile AMidot array	x	
Mikrogen Diagn.	recomLine ANA/ENA		
Theradiag	ENA Dot 7 ENALISA		
Phadia/ThermoSc	Elia Ro		

	IDENTIFICATIE – Methode 1						
	Recombinant	Natief	Synthetisch	Concentratie*	Eenheid	Cut-off	Besluit +, +/-, -
SSA (Ro)							
Ro-52							
Ro-60							
SSB (La)							
Sm							

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Anti-ENA - other tests

		Identificatie	Concen-tratie	Eenheid	Cut-off	+, - of +/-
4010	Methode te preciseren Type : ANA-17 Pro Code : 329 Naam kit : AESKU BLOT	SSA/Ro60 SSA/Ro52 SSB/La				+ + +

Fill in blot/ELISA/CLIA… in identification

ACKNOWLEDGEMENTS

Expert committee NIS

QUESTIONS?

SUGGESTIONS?

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Presentations will become available on the Sciensano website

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