


Individual Report		QCMD 2017 Sexually Transmitted Infections I EQA Pilot Study					
Catalogue Code: QAB154177	Ref Code: STI_I17	Challenge: S	Analysis Type: Multiple Pathogen Qualitative	Dataset: 186582	Report UID: 2677/7630/1258	Laboratory CZ023	

Intended Results / Panel Composition

Sample Code	Sample Contents	Sample Matrix	Sample Relationship ^[1]	Detected / Determined ^[2]		Not Detected / Not Determined ^[2]		Not Tested ^[2]	
				(%)	(n)	(%)	(n)	(%)	(n)
STI_I17S-01	Mycoplasma hominis	Transport Medium		51.3	61	2.5	3	46.2	55
STI_I17S-02	Trichomonas vaginalis	Transport Medium	DS1_2	86.6	103	2.5	3	10.9	13
STI_I17S-03	Ureplasma urealyticum	Transport Medium		47.9	57	3.4	4	48.7	58
STI_I17S-04	Mycoplasma genitalium	Transport Medium	DS2_2	83.2	99	4.2	5	12.6	15
STI_I17S-05	Trichomonas vaginalis	Transport Medium	DS1_1	88.2	105	2.5	3	9.2	11
STI_I17S-06	Negative	Transport Medium		99.2	118	0.8	1	N/A	0
STI_I17S-07	Trichomonas vaginalis	Transport Medium	DS1_3	70.6	84	20.2	24	9.2	11
STI_I17S-08	Gardnerella vaginalis	Transport Medium		16.8	20	4.2	5	79	94
STI_I17S-09	Mycoplasma genitalium	Transport Medium	DS2_1	85.7	102	1.7	2	12.6	15

[1] **Sample Relationship:** Indicates the relationships of the samples within this challenge. Dilution series are indicated by 'DS1' with each panel member in the dilution series represented by a number in order of titre, where DS1_1 represents the highest titre within that dilution series. Further dilution series are indicated by 'DS2' 'DS3' etc. If one duplicate pair is present this is indicated by 'D1'. Further duplicate pairs are indicated by 'D2', 'D3' etc.

[2] **Detected / Determined; Not Detected / Not Determined; Not Tested:** The percentage (%) of datasets reported by all participants in relation to the assigned status of the panel member i.e. 'positive' or 'negative' and the expected pathogen type as defined through pre-testing and the total number of datasets (n) for each panel member.

For further details please refer to the current participant manual.

EQA Assessment Group^[1]	N/A (Refer to My Workflow details section below)
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Your Summary Results

Individual Report

QCMD 2017 Sexually Transmitted Infections I EQA Pilot Study



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Sample Code	Expected Result ^[2]		Your Final Laboratory Reported Result ^[3]		
	Qualitative	Pathogen ID	Pathogen included in workflow(s) ^[4] Yes/No	Qualitative ^[5]	Reported Pathogen ID ^[6]
STI_I17S-01	Positive	Mycoplasma hominis	Yes	Positive	Mycoplasma hominis
STI_I17S-02	Positive	Trichomonas vaginalis	No	Negative	
STI_I17S-03	Positive	Ureaplasma urealyticum	Yes	Positive	Ureaplasma urealyticum
STI_I17S-04	Positive	Mycoplasma genitalium	Yes	Positive	Mycoplasma genitalium
STI_I17S-05	Positive	Trichomonas vaginalis	No	Negative	
STI_I17S-06	Negative		N/A	Negative	
STI_I17S-07	Positive	Trichomonas vaginalis	No	Negative	
STI_I17S-08	Positive	Gardnerella vaginalis	No	Negative	
STI_I17S-09	Positive	Mycoplasma genitalium	Yes	Positive	Mycoplasma genitalium

[1] **EQA Assessment Group:** To aid analysis participant results are grouped according to the molecular amplification/ detection method specified within their molecular workflow for this challenge/ distribution. For further details refer to the Additional Information: Individual Panel Member Analysis section of this report.

[2] **Expected result:** positive / negative result and the specific pathogen present within each panel member.


[3] **Your Final Laboratory Reported Result:** the final reported result which may be based on one or more workflows used to test each panel member.

[4] **Pathogen included in workflow(s):** Yes / No answer to whether the expected pathogen was tested for.

[5] **Qualitative:** The final qualitative result you reported for each sample within this EQA challenge / distribution.

[6] **Reported Pathogen ID:** The final pathogen(s) identification you reported for each sample within this EQA challenge / distribution.

For further details please refer to the current participant manual.


Individual Report	QCMD 2017 Sexually Transmitted Infections I EQA Pilot Study				 <small>Quality Control for Molecular Diagnostics</small>	
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Multiple Pathogen Programme - Qualitative



Assessment of Results

Results are categorised based on the workflow used and the pathogen(s) targeted as shown in the table below.

Expected Qualitative Result	Participant Reported Results						Result Category	
	Positive	Negative	Not Determined	Expected pathogen(s) included in workflow(s)		Expected pathogen(s) not included in workflow(s)		
				Expected pathogen(s) detected	Expected pathogen(s) not detected	Unexpected pathogen(s) detected		
Positive	✓			✓			Expected Pathogen Reported	Detected / Determined
Negative		✓					No pathogen reported	
Negative	✓						False positive	Not Detected / Not Determined
Positive	✓					✓	Reported Pathogen(s) not as expected	
Positive		✓			✓		No pathogen reported	
Positive	✓				✓		Reported Pathogen(s) not as expected	
Positive or Negative			✓				Result reported as not determined	
Positive		✓				✓	Expected pathogen not tested for	Not Tested

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My workflow details:

Name	STI (v4)
Description	
Targets	<ul style="list-style-type: none"> B Mycoplasma genitalium B Ureaplasma parvum B Ureaplasma urealyticum B Mycoplasma hominis
Assays	<ul style="list-style-type: none">  Extraction - GeneProof - GeneProof <ul style="list-style-type: none"> • Commercial <ul style="list-style-type: none"> ◦ Kit Manufacturer: <i>GeneProof</i> ◦ Kit Type: <i>croBEE 201A Nucleic Acid Extraction Kit</i>  Amplification - Shanghai Hongshi Medical Technology - SLAN <ul style="list-style-type: none"> • Commercial <ul style="list-style-type: none"> ◦ Kit Manufacturer: <i>GeneProof</i> ◦ Kit Type: <i>GeneProof Mycoplasma genitalium/hominis PCR Kit and GeneProof Ureaplasma species PCR Kit</i> ◦ Kit Version: <i>ISEX</i>


Used to test samples:	STI_I17S-01, STI_I17S-02, STI_I17S-03, STI_I17S-04, STI_I17S-05, STI_I17S-06, STI_I17S-07, STI_I17S-08, STI_I17S-09
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Further Programme Details

Number of Participants	125
Number of Countries	28
Number of Respondents	114
Number of Datasets Submitted	119

Comments

In the field of STI testing laboratories employ a range of testing protocols, where multiplex assays and multiple workflows may be employed to test the samples for different pathogens. In some instances this will result in a large number of workflows which are classified as not tested when a lab does not test for one or all of the pathogens included in a sample.

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EQA Programme Aims

To assess the laboratory's ability to detect a range of sexually transmitted infections known to cause disease using their routine molecular diagnostic platform and procedures.

Feedback and Enquiries

Participants are encouraged to read the QCMD Participants' Manual, which can be downloaded from the QCMD website.

Any queries about this report should be addressed to the QCMD Neutral Office (neutraloffice@qcmd.org).

Additional Information: Individual Panel Member Analysis

Qualitative analysis for each panel member is provided in relation to your EQA assessment group. EQA assessment groups are established using the molecular workflow information reported by all participants within this EQA challenge / distribution.

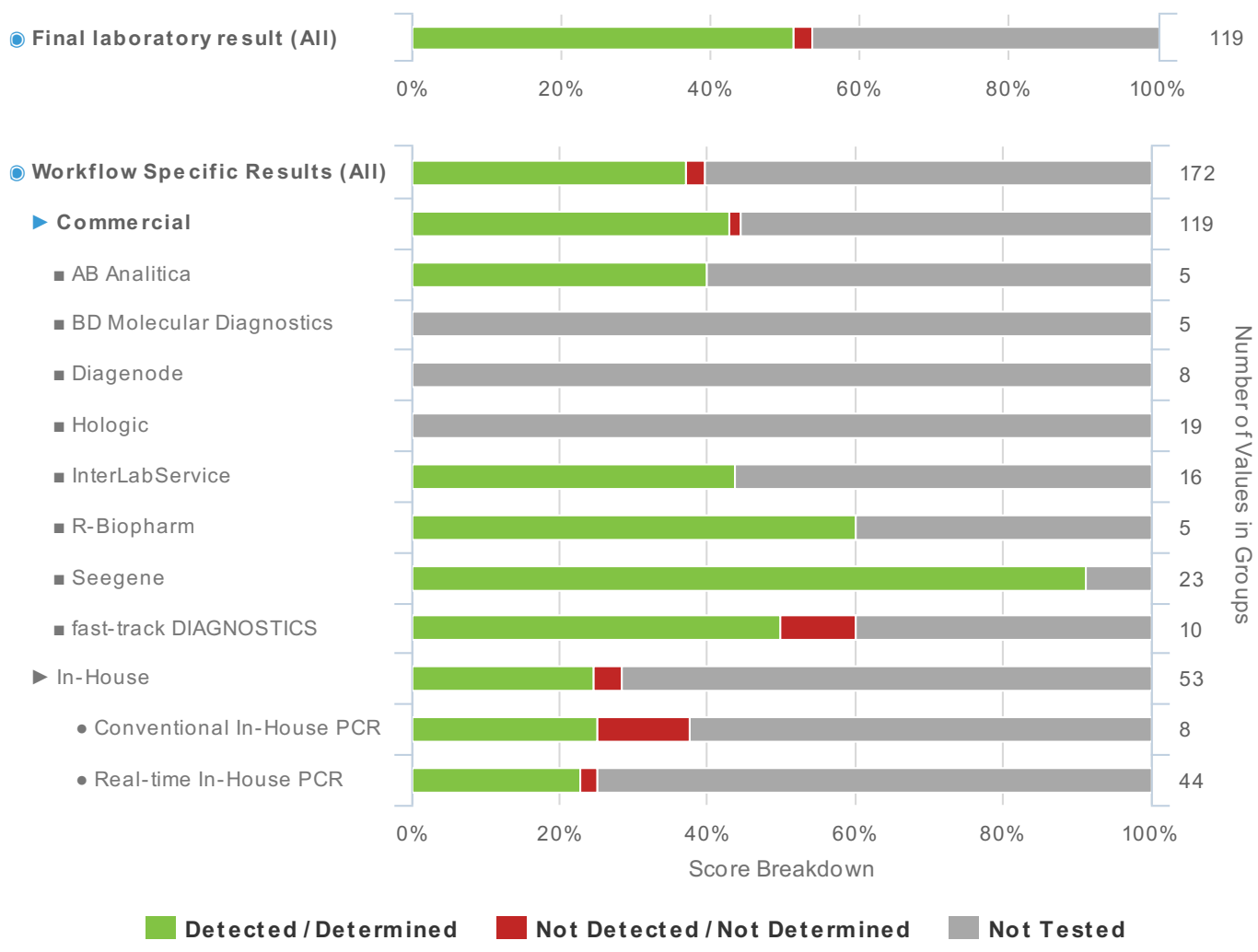
To allow meaningful assessment at the individual method level the EQA assessment group must consist of 5 or more datasets. If there are not sufficient datasets at the individual method level then your results will be included within a higher EQA assessment group based on whether it is a commercial or in house technology/method. The highest level assessment grouping is "All" participant reported qualitative results.


A breakdown of qualitative results reported for all workflows used by participants on each of the panel members within this EQA challenge / distribution is provided below. Note: participants may use multiple workflows for each sample.

The final laboratory result indicates the final reported result which may be based on one or more workflows used to test each panel member.

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Sample Code	Sample Contents	Sample Matrix	Sample Relationship	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	(n)	(%)	(n)	(%)	(n)
STI_I17S-01	Mycoplasma hominis	Transport Medium		Mycoplasma hominis	51.3	61	2.5	3	46.2	55



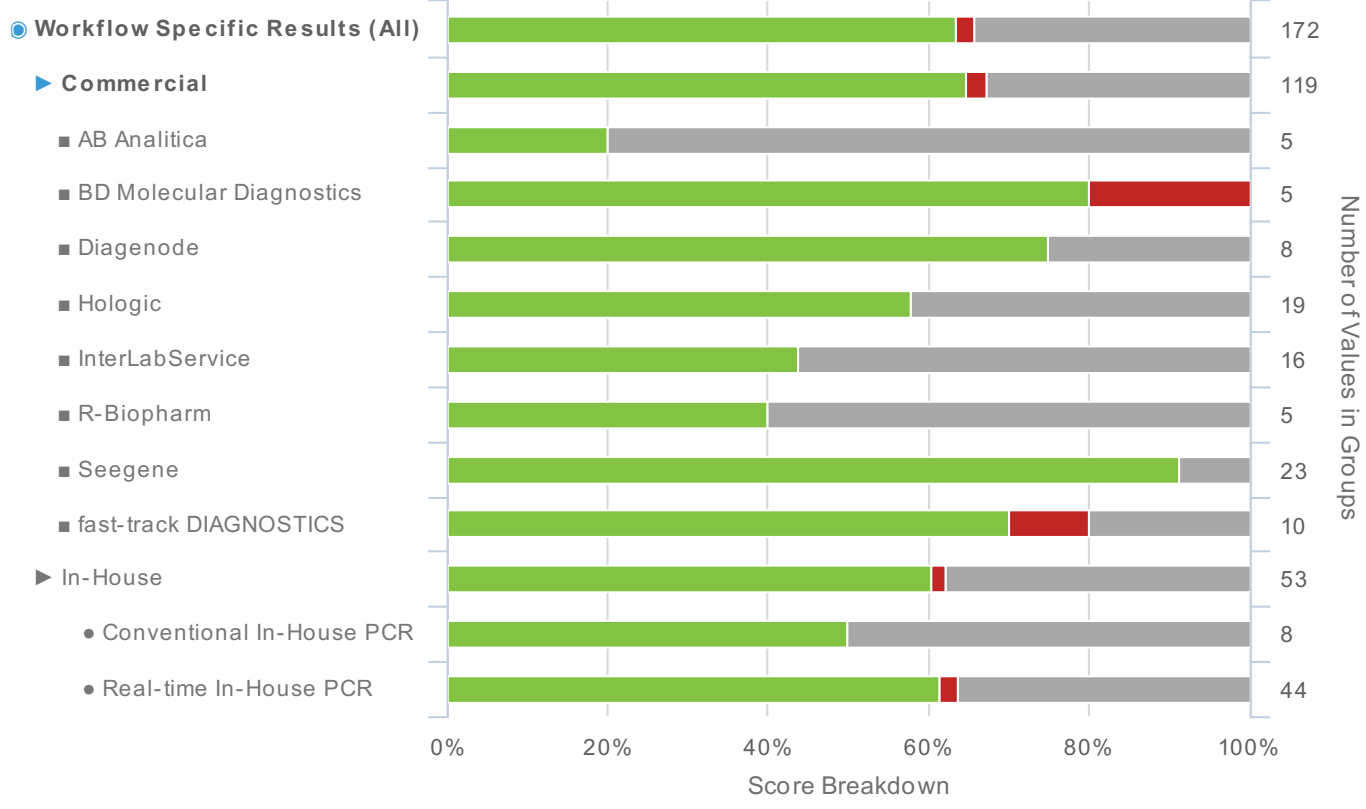
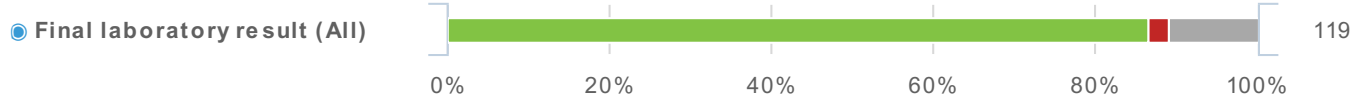
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Groups below n=5: AusDiagnostics (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=1), BIORON (n=3), BIORON - BIORON RealLine (n=3), Cepheid (n=2), Cepheid - Cepheid Xpert kit (n=2), Certest (n=2), Certest - Certest Real Time PCR (n=2), DiagCor (n=1), DiagCor - DiagCor GenoFlow (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), Genetic Signatures (n=1), Genetic Signatures - Genetic Signatures Easyscreen (n=1), HybriBio (n=1), HybriBio - Multiplex Commercial PCR (n=1), Master Diagnostica (n=1), Master Diagnostica - Master Diagnostica Flow Chip (n=1), PathoFinder (n=1), PathoFinder - PathoFinder Real Time PCR (n=1), PrimerDesign (n=1), PrimerDesign - PrimerDesign Genesig (n=1), Progenie Molecular (n=1), Progenie Molecular - Progenie Molecular RealCycler (n=1), Randox (n=1), Randox - Randox Multiplex Array (n=1), Sacace (n=2), Sacace - Sacace Real TM (n=2), Speedx (n=1), Speedx - Speedx Real Time PCR (n=1), TIB MOLBIOL (n=4), TIB MOLBIOL - TIB-MolBioI LightMix (n=4), Vitassay (n=2), Vitassay - Vitassay Real-Time PCR (n=2), savyonDIAGNOSTICS (n=1), savyonDIAGNOSTICS - savyonDIAGNOSTICS NanoCHIP (n=1), In-House - In-House Conventional and Real-time PCR (n=1)

Groups Rolled Up: AB Analytica - AB Analytica REALQUALITY RQ (n=5), BD Molecular Diagnostics - BD ProbeTec (n=5), Diagenode - Diagenode Real Time kit (n=8), Hologic - Hologic Aptima (n=19), InterLabService - InterLabService AmpliSens (n=16), R-Biopharm - R-Biopharm RIDA Gene (n=5), Seegene - Seegene Real Time PCR (n=23), fast-track DIAGNOSTICS - FTD real time PCR (n=10)

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STI_I17S-02	Trichomonas vaginalis	Transport Medium	DS1_2	Trichomonas vaginalis	86.6	103	2.5	3	10.9	13



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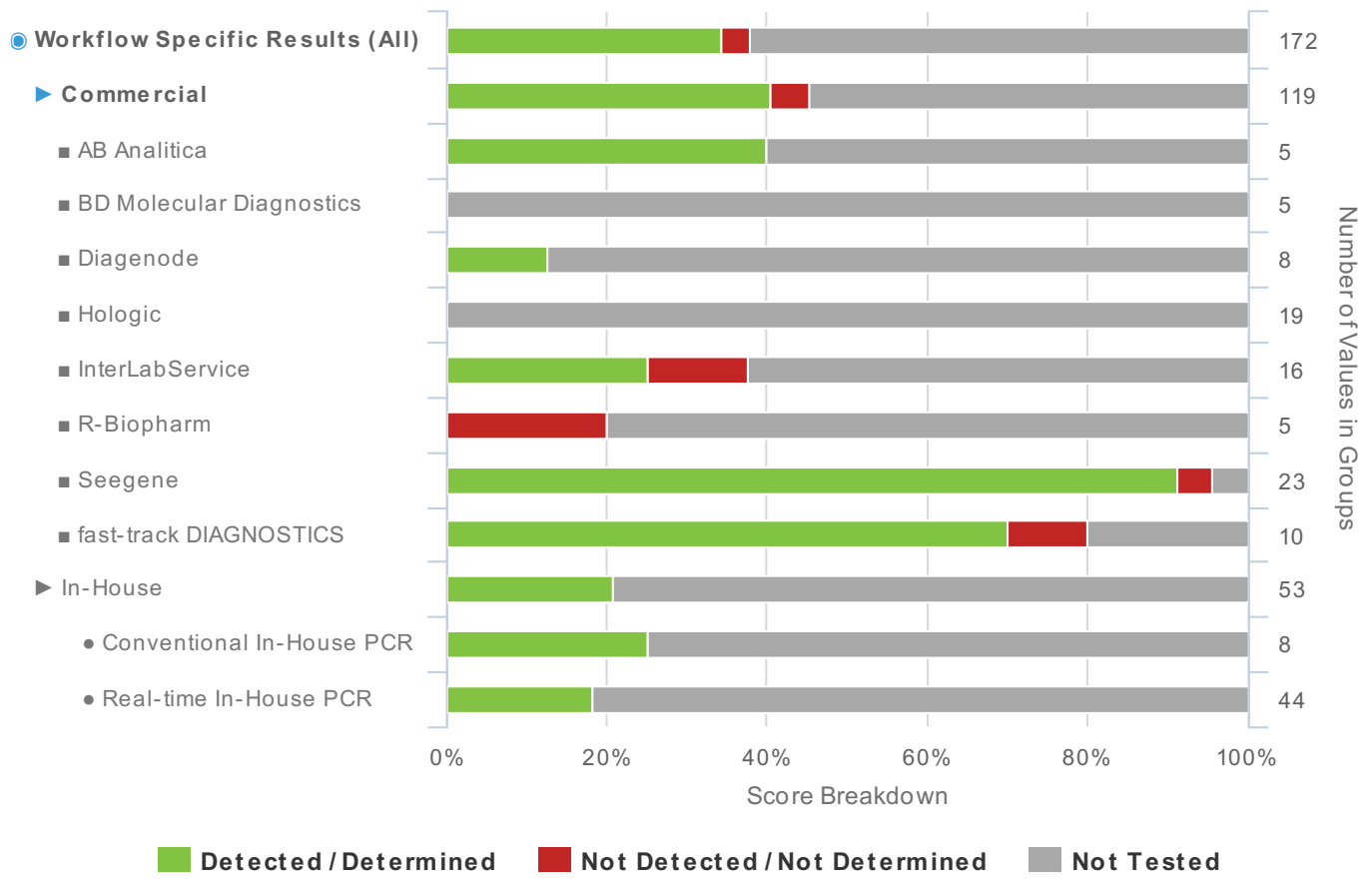
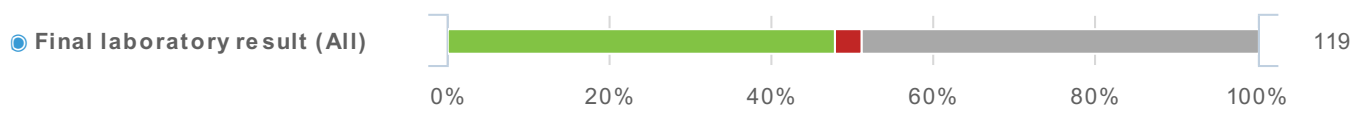
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STI_I17S-03	Ureaplasma urealyticum	Transport Medium		Ureaplasma urealyticum	47.9	57	3.4	4	48.7	58



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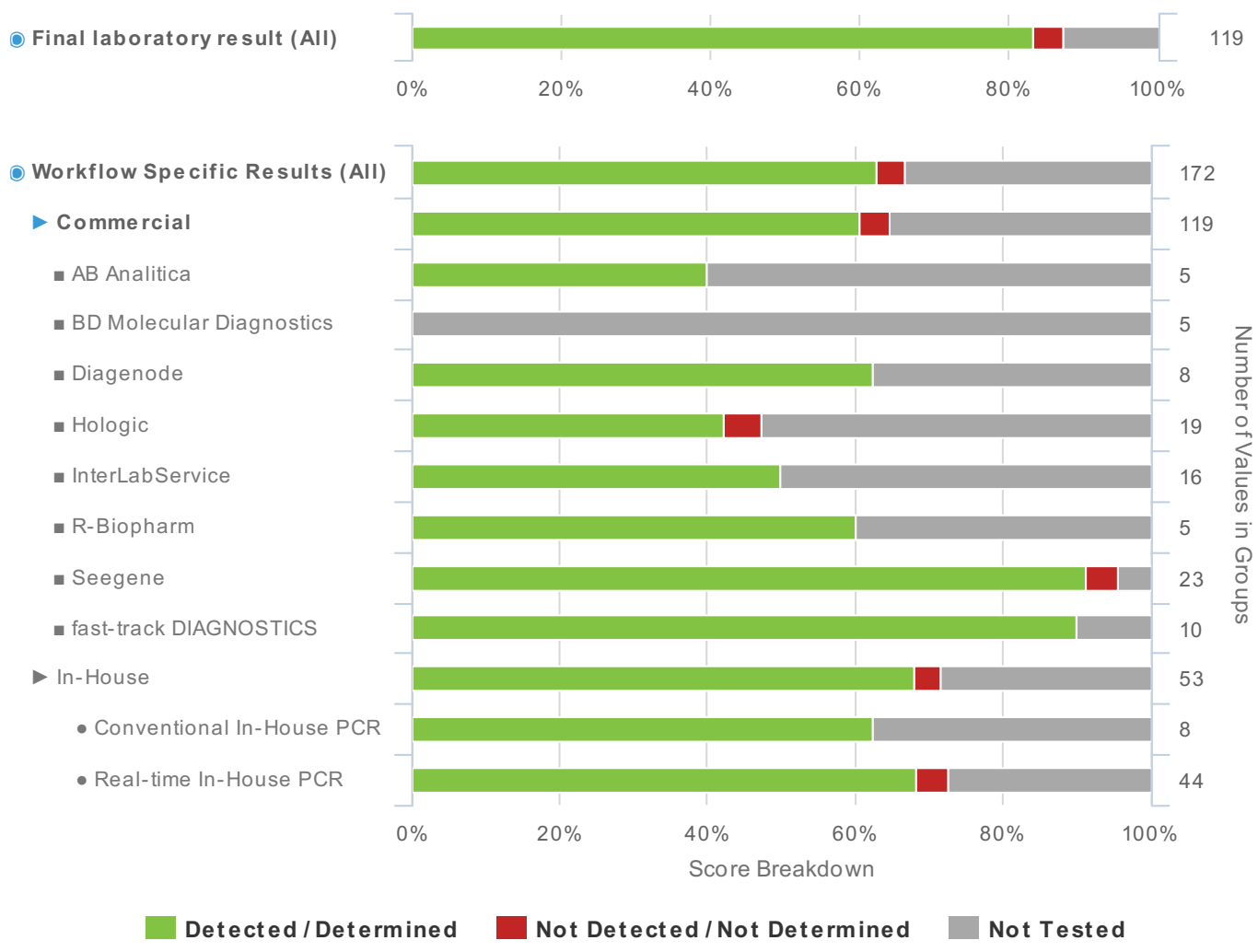
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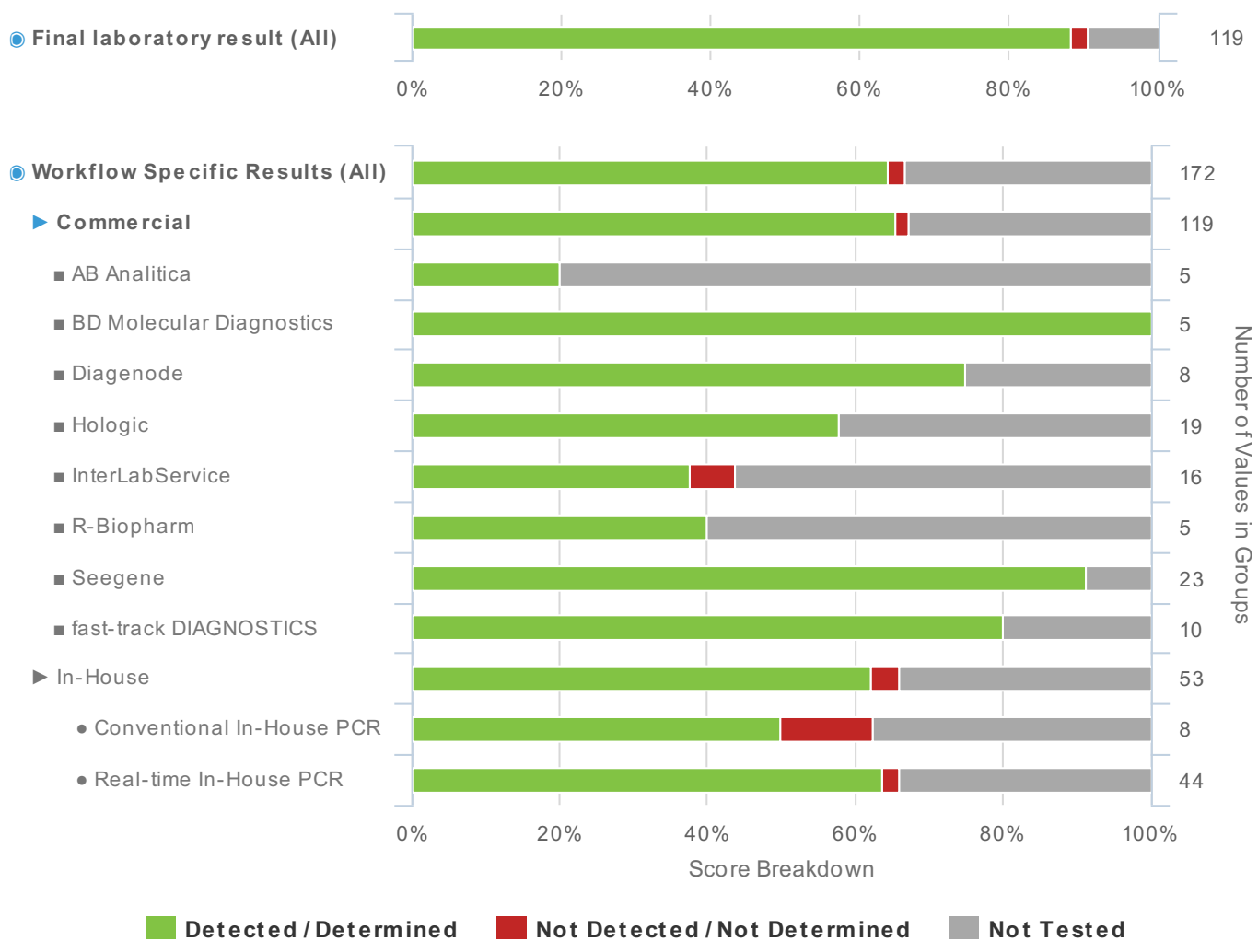
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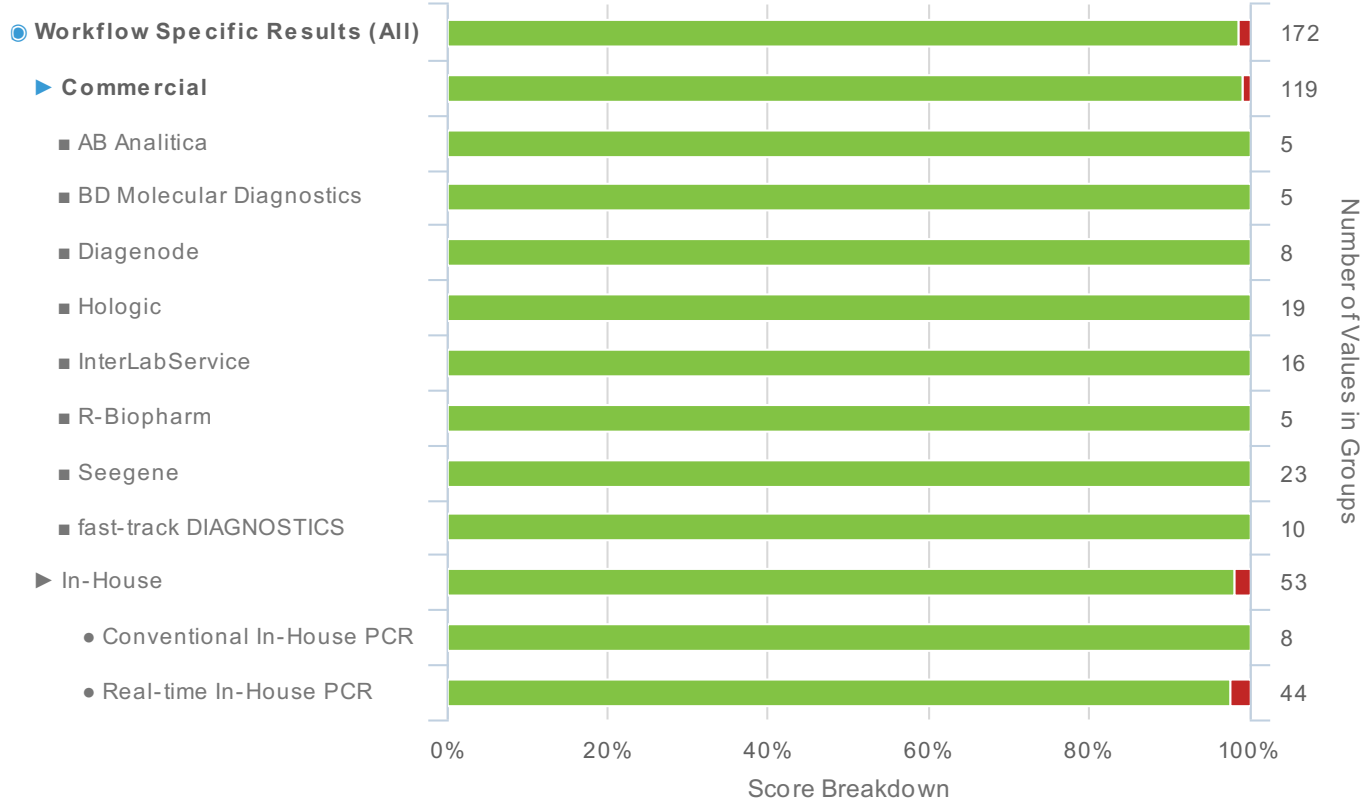
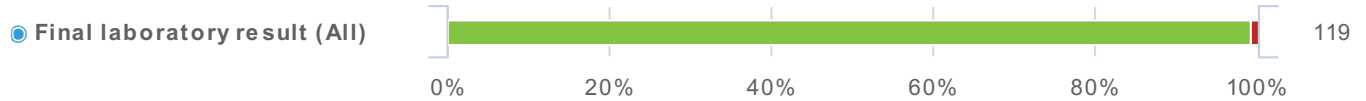
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■ Detected / Determined
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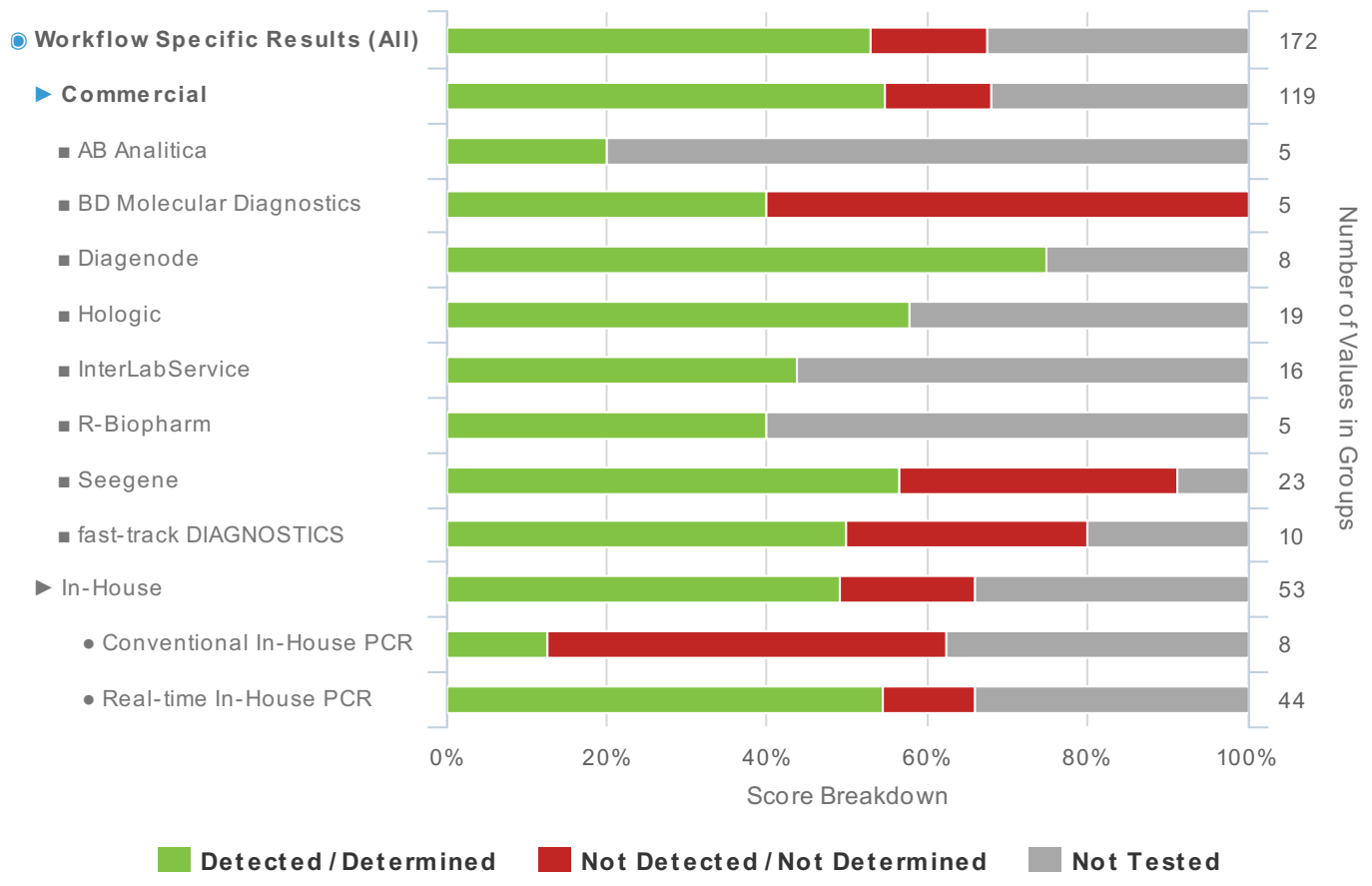
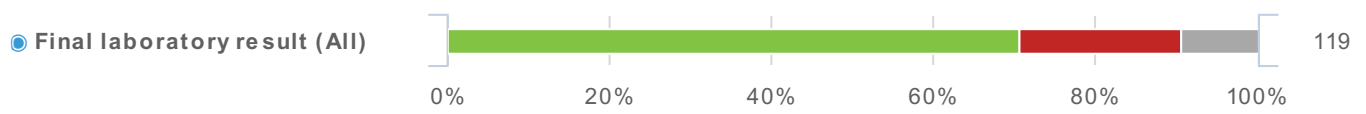
Individual Report	QCMD 2017 Sexually Transmitted Infections I EQA Pilot Study				 <small>Quality Control for Molecular Diagnostics</small>	
	Catalogue Code: QAB154177	Ref Code: STI_I17	Challenge: S	Analysis Type: Multiple Pathogen Qualitative	Dataset: 186582	Report UID: 2677/7630/1258


Groups below n=5: AusDiagnostics (n=1), AusDiagnostics - AusDiagnostics Easy-Plex (n=1), BIORON (n=3), BIORON - BIORON RealLine (n=3), Cepheid (n=2), Cepheid - Cepheid Xpert kit (n=2), Certest (n=2), Certest - Certest Real Time PCR (n=2), DiagCor (n=1), DiagCor - DiagCor GenoFlow (n=1), GeneProof (n=2), GeneProof - GeneProof Real Time PCR kit (n=2), Genetic Signatures (n=1), Genetic Signatures - Genetic Signatures Easyscreen (n=1), HybriBio (n=1), HybriBio - Multiplex Commercial PCR (n=1), Master Diagnostica (n=1), Master Diagnostica - Master Diagnostica Flow Chip (n=1), PathoFinder (n=1), PathoFinder - PathoFinder Real Time PCR (n=1), PrimerDesign (n=1), PrimerDesign - PrimerDesign Genesig (n=1), Progenie Molecular (n=1), Progenie Molecular - Progenie Molecular RealCycler (n=1), Randox (n=1), Randox - Randox Multiplex Array (n=1), Sacace (n=2), Sacace - Sacace Real TM (n=2), Speedx (n=1), Speedx - Speedx Real Time PCR (n=1), TIB MOLBIOL (n=4), TIB MOLBIOL - TIB-MolBioI LightMix (n=4), Vitassay (n=2), Vitassay - Vitassay Real-Time PCR (n=2), savyonDIAGNOSTICS (n=1), savyonDIAGNOSTICS - savyonDIAGNOSTICS NanoCHIP (n=1), In-House - In-House Conventional and Real-time PCR (n=1)

Groups Rolled Up: AB Analytica - AB Analytica REALQUALITY RQ (n=5), BD Molecular Diagnostics - BD ProbeTec (n=5), Diagenode - Diagenode Real Time kit (n=8), Hologic - Hologic Aptima (n=19), InterLabService - InterLabService AmpliSens (n=16), R-Biopharm - R-Biopharm RIDA Gene (n=5), Seegene - Seegene Real Time PCR (n=23), fast-track DIAGNOSTICS - FTD real time PCR (n=10)

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Sample Code	Sample Contents	Sample Matrix	Sample Relationship	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	(n)	(%)	(n)	(%)	(n)
STI_I17S-07	Trichomonas vaginalis	Transport Medium	DS1_3	Trichomonas vaginalis	70.6	84	20.2	24	9.2	11



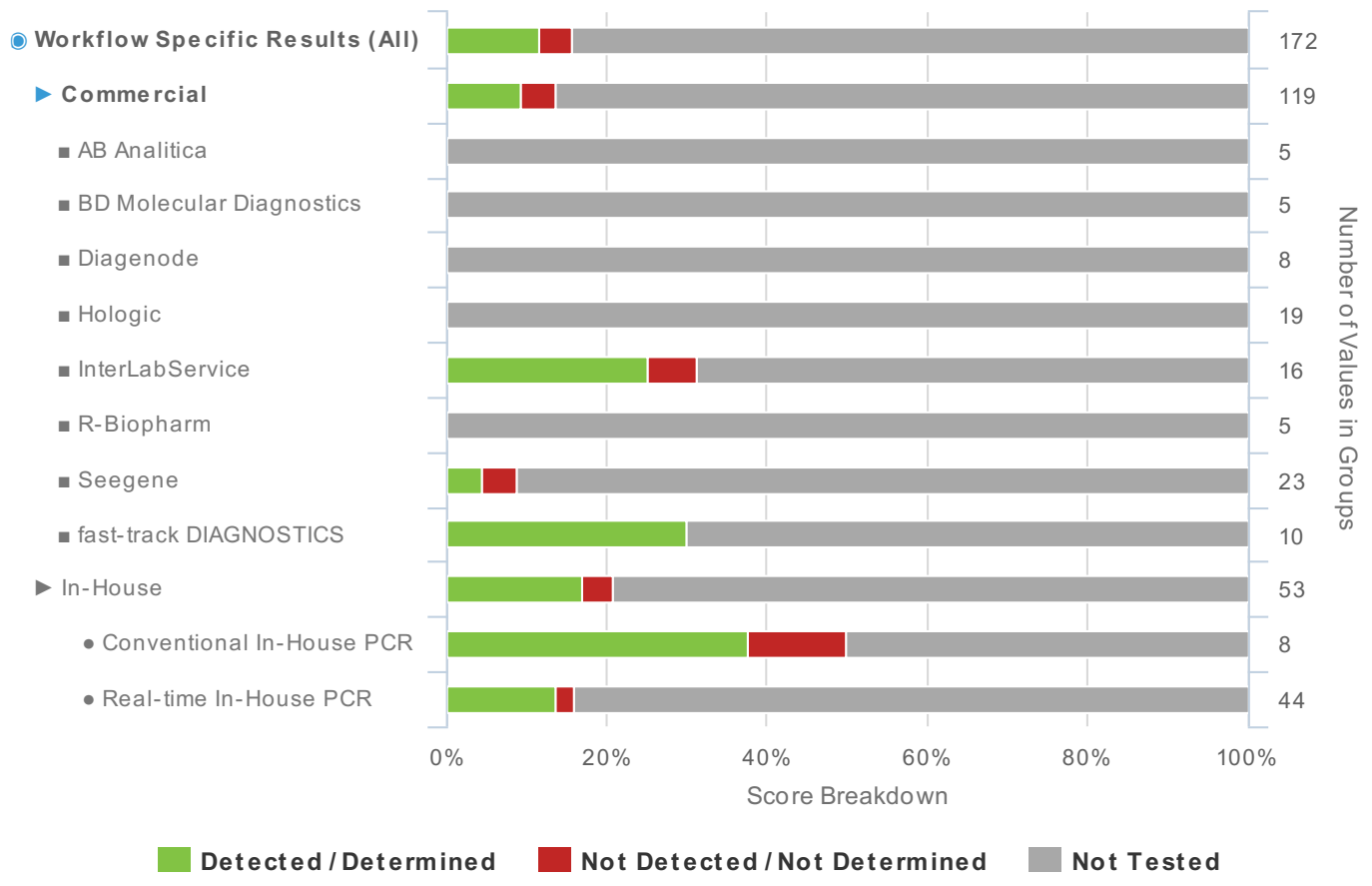
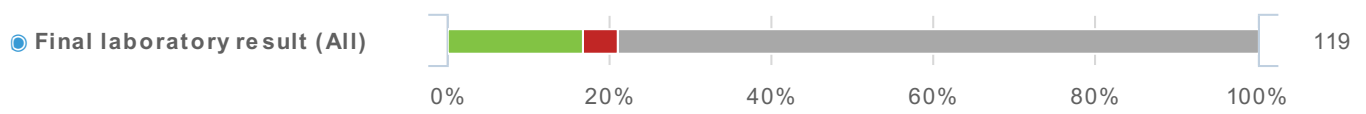
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Sample Code	Sample Contents	Sample Matrix	Sample Relationship	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	(n)	(%)	(n)	(%)	(n)
STI_I17S-08	Gardnerella vaginalis	Transport Medium		Gardnerella vaginalis	16.8	20	4.2	5	79	94



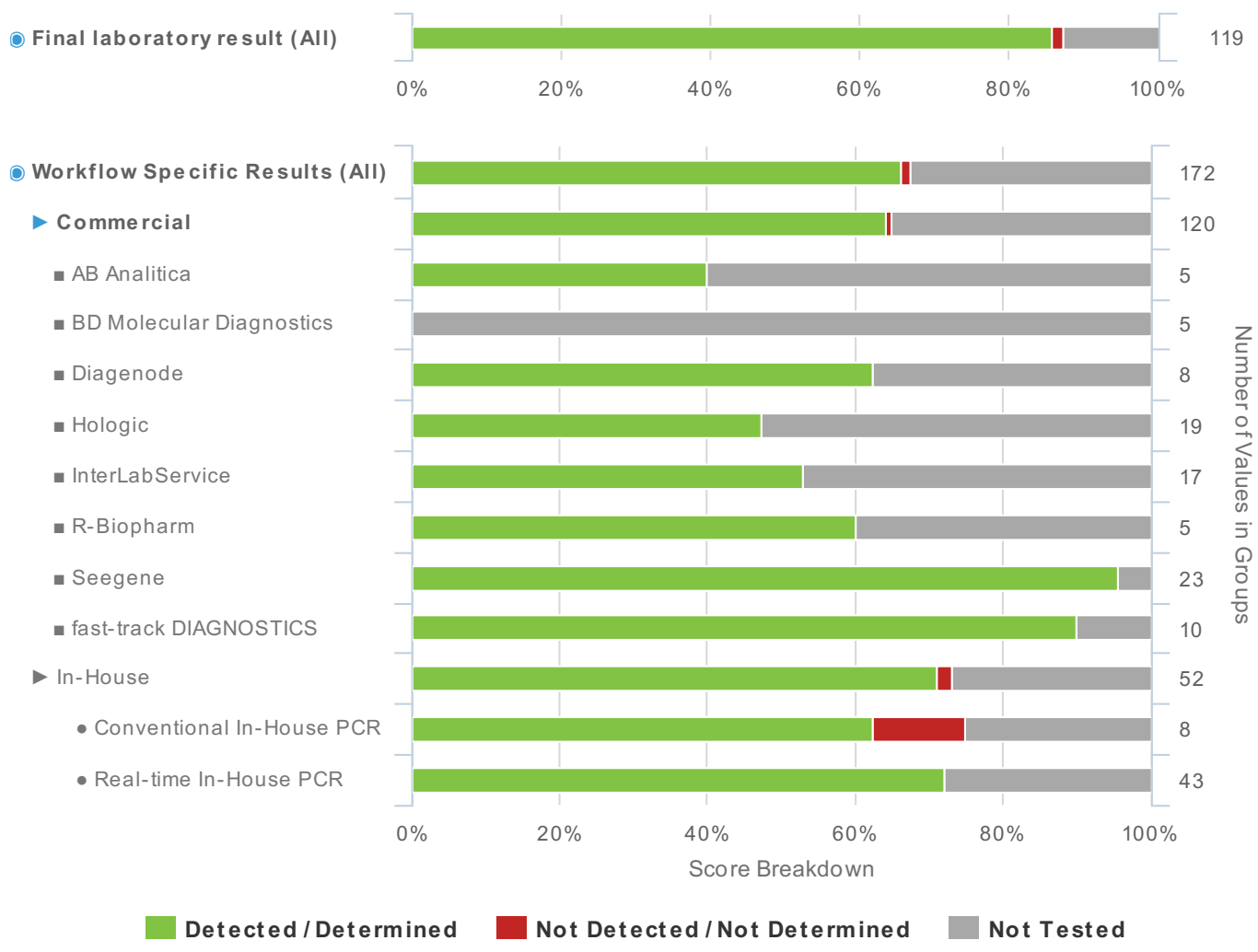
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					(%)	(n)	(%)	(n)	(%)	(n)
STI_I17S-09	Mycoplasma genitalium	Transport Medium	DS2_1	Mycoplasma genitalium	85.7	102	1.7	2	12.6	15



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