

# Individual Report

# QCMD 2018 Sexually Transmitted Infections I EQA Pilot Study



<b>Catalogue Code:</b> QAB154177	<b>Ref Code:</b> STI_I18	<b>Challenge:</b> S	<b>Analysis Type:</b> Multiple Pathogen Qualitative	<b>Dataset:</b> 256978	<b>Report UID:</b> 2677/16299/1846	<b>Laboratory:</b> CZ023
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## Panel Composition

Sample Code	Sample Content	Matrix	Sample Relationships <sup>[1]</sup>	Detected / Determined <sup>[2]</sup>		Not Detected / Not Determined <sup>[2]</sup>		Not Tested <sup>[2]</sup>	
				(%)	(n)	(%)	(n)	(%)	(n)
STI_I18S-01	Trichomonas vaginalis	Transport Medium	DS1_2	80.9	93	4.3	5	14.8	17
STI_I18S-02	Trichomonas vaginalis	Transport Medium	DS1_1	82.6	95	2.6	3	14.8	17
STI_I18S-03	Ureaplasma urealyticum	Transport Medium		60	69	2.6	3	37.4	43
STI_I18S-04	Trichomonas vaginalis	Transport Medium	DS1_3	58.3	67	27.8	32	13.9	16
STI_I18S-05	Mycoplasma hominis	Transport Medium		60.9	70	7	8	32.2	37
STI_I18S-06	Mycoplasma genitalium (drug resistant)	Transport Medium		85.2	98	4.3	5	10.4	12
STI_I18S-07	Mycoplasma genitalium	Transport Medium		86.1	99	4.3	5	9.6	11
STI_I18S-08	Chlamydia trachomatis and Mycoplasma hominis	Transport Medium		33	38	16.5	19	50.4	58
STI_I18S-09	Negative	Transport Medium		96.5	111	3.5	4	N/A	0
STI_I18S-10	Gardnerella vaginalis	Transport Medium		18.3	21	6.1	7	75.7	87

[1] **Sample Relationships:** Indicates the relationships of the samples within this challenge. The highest titre member of dilution series DS1 is indicated by DS1\_1 and further members of the series as DS1\_2, DS1\_3 etc. in order of reducing titre. Additional dilution series are indicated by DS2 (e.g DS2\_1, DS2\_2 etc.), DS3 (e.g. DS3\_1, DS3\_2 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.*

<b>EQA Assessment Group<sup>[1]</sup></b>	N/A (Refer to <b>My Workflow details</b> section below)
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## Your Summary Results

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Sample Code	Expected Result <sup>[2]</sup>		Your Final Laboratory Reported Result <sup>[3]</sup>		
	Qualitative	Pathogen ID	Pathogen included in workflow(s) <sup>[4]</sup> Yes/No	Qualitative <sup>[5]</sup>	Reported Pathogen ID <sup>[6]</sup>
STI_I18S-01	Positive	Trichomonas vaginalis	No	Negative	
STI_I18S-02	Positive	Trichomonas vaginalis	No	Negative	
STI_I18S-03	Positive	Ureaplasma urealyticum	No	Negative	
STI_I18S-04	Positive	Trichomonas vaginalis	No	Negative	
STI_I18S-05	Positive	Mycoplasma hominis	No	Negative	
STI_I18S-06	Positive	Mycoplasma genitalium	Yes	Positive	Mycoplasma genitalium
STI_I18S-07	Positive	Mycoplasma genitalium	Yes	Positive	Mycoplasma genitalium
STI_I18S-08	Positive	Mycoplasma hominis and Chlamydia trachomatis	No	Positive	Chlamydia trachomatis
STI_I18S-09	Negative		N/A	Negative	
STI_I18S-10	Positive	Gardnerella vaginalis	No	Negative	

[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.**


<b>Individual Report</b>		<b>QCMD 2018 Sexually Transmitted Infections I EQA Pilot Study</b>			 <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	Laboratory 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			
Positive	✓			✓			Expected Pathogen Reported	Detected / Determined
Negative		✓					No pathogen reported	Detected / Determined
Negative	✓						False Positive	False Positive
Positive	✓					✓	Reported Pathogen(s) not as expected	False Positive
Positive	✓				✓		Reported Pathogen(s) not as expected	False Positive
Positive or Negative			✓				Result reported as not determined	Not Determined
Positive		✓			✓		No pathogen reported	False Positive
Positive		✓				✓	Expected pathogen not tested for	Not Tested

<b>Individual Report</b>		<b>QCMD 2018 Sexually Transmitted Infections I EQA Pilot Study</b>			 <small>Quality Control for Molecular Diagnostics</small>	
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### My Workflow Details:

<b>Name</b>	STI-CNMX (v2)
<b>Description</b>	
<b>Targets</b>	<ul style="list-style-type: none"> <li><span style="background-color: #c8e6c9; border-radius: 50%; padding: 2px;">B</span> Mycoplasma genitalium</li> <li><span style="background-color: #c8e6c9; border-radius: 50%; padding: 2px;">B</span> Neisseria gonorrhoeae</li> <li><span style="background-color: #c8e6c9; border-radius: 50%; padding: 2px;">B</span> Chlamydia trachomatis</li> </ul>
<b>Assays</b>	<ul style="list-style-type: none"> <li><span style="color: #0070c0;">DNA</span> <b>Extraction</b> - Manual Extraction Process <ul style="list-style-type: none"> <li>• Commercial <ul style="list-style-type: none"> <li>◦ Kit Manufacturer: <i>GeneProof</i></li> <li>◦ Kit Type: <i>PathogenFree DNA Isolation Kit</i></li> </ul> </li> </ul> </li> <li><span style="color: #0070c0;">RNA</span> <b>Amplification</b> - GeneProof - croBEE Real-Time PCR System <ul style="list-style-type: none"> <li>• Multiplex</li> <li>• Commercial <ul style="list-style-type: none"> <li>◦ Kit Manufacturer: <i>GeneProof</i></li> <li>◦ Kit Type: <i>GeneProof CNMX PCR Kit</i></li> <li>◦ Kit Version: <i>ISEX</i></li> </ul> </li> </ul> </li> </ul>


<b>Used to test samples:</b>	STI_I18S-01, STI_I18S-02, STI_I18S-03, STI_I18S-04, STI_I18S-05, STI_I18S-06, STI_I18S-07, STI_I18S-08, STI_I18S-09, STI_I18S-10
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### Further Programme Details

Number of Participants	109
Number of Countries	32
Number of Respondents	101
Number of Datasets Submitted	115

### 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](mailto: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.

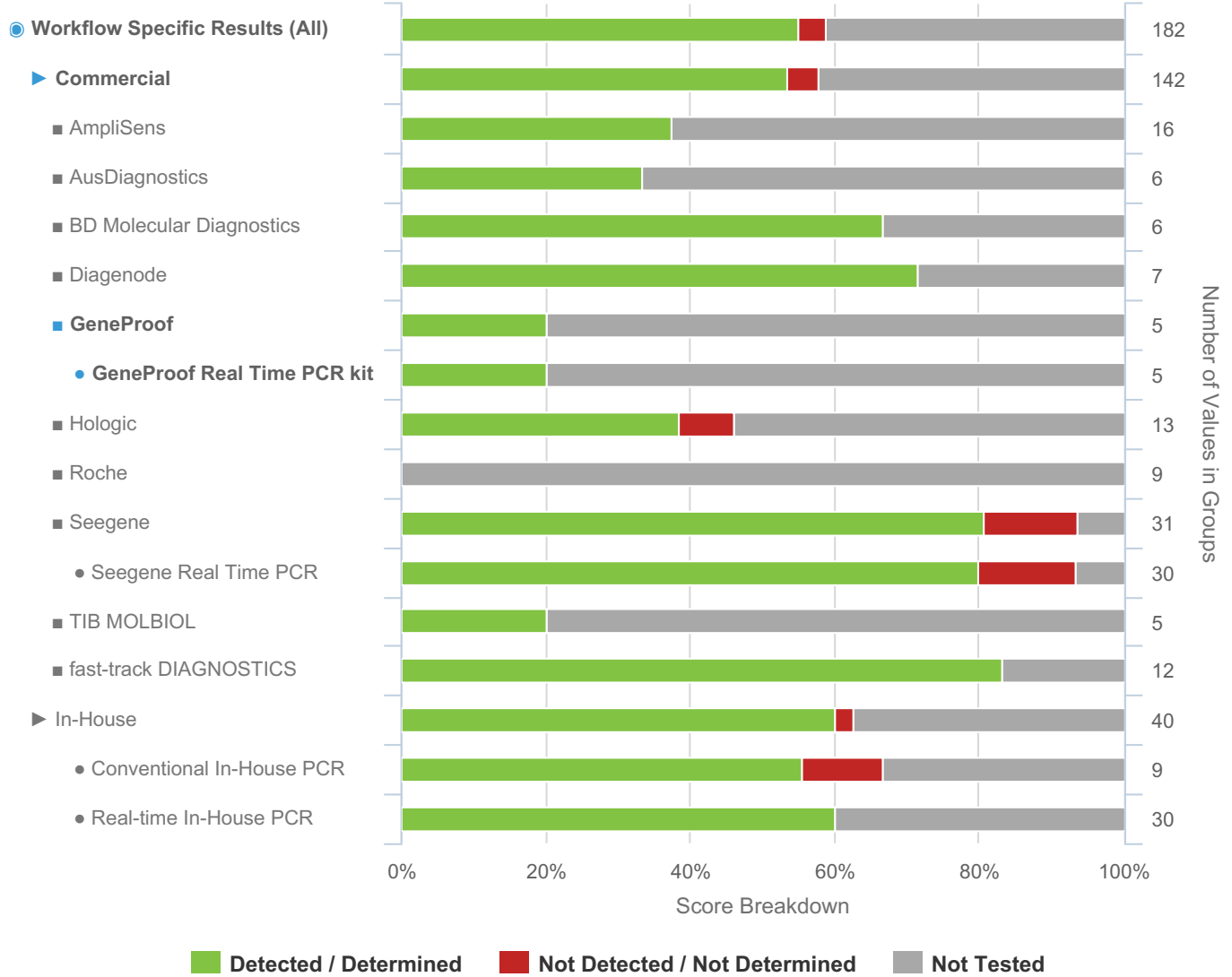
To allow meaningful assessment at the individual method level the EQA assessment group must consist of 5 or more datasets. If there are not sufficient datasets at the individual method level then your results will be included within a higher EQA assessment group based on whether it is a commercial or 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 Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	(n)	(%)	(n)	(%)	(n)
STI_I18S-01	Trichomonas vaginalis	Transport Medium	DS1_2	Trichomonas vaginalis	80.9	93	4.3	5	14.8	17



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**Groups below n=5:** AB Analytica (n=4), AB Analytica - AB Analytica REALQUALITY RQ (n=4), Abbott (n=2), Abbott - Abbott Real Time PCR (n=2), Anatolia Geneworks (n=1), Anatolia Geneworks - Anatolia Geneworks Bosphore (n=1), Applied Biosystems (n=1), Applied Biosystems - Applied Biosystems Real Time PCR (n=1), BD Molecular Diagnostics - BD MAX (n=4), BD Molecular Diagnostics - BD ProbeTec (n=2), BIORON (n=3), BIORON - BIORON RealLine (n=3), BioGX (n=2), BioGX - BioGX Sample-Ready (n=2), Cepheid (n=2), Cepheid - Cepheid Xpert kit (n=2), DiagCor (n=1), DiagCor - DiagCor GenoFlow (n=1), Genetic Signatures (n=1), Genetic Signatures - Genetic Signatures Easyscreen (n=1), Hong Kong CH Gene (n=1), Hong Kong CH Gene - HK CH Gene Real Time PCR (n=1), HybriBio (n=1), HybriBio - Multiplex Commercial PCR (n=1), PrimerDesign (n=1), PrimerDesign - PrimerDesign Genesig (n=1), Progenie Molecular (n=1), Progenie Molecular - Progenie Molecular RealCycler (n=1), R-Biopharm (n=4), R-Biopharm - R-Biopharm RIDA Gene (n=4), Randox (n=1), Randox - Randox Multiplex Array (n=1), Roche - Roche Cobas 4800 (n=1), Roche - Roche Cobas 6800/8800 (n=4), Roche - Roche Cobas Amplicor (n=1), Roche - Roche LightCycler (n=3), Sacace (n=4), Sacace - Sacace Real TM (n=4), Seegene - Seegene Seeplex (n=1), SpeeDx (n=2), SpeeDx - SpeeDx Real Time PCR (n=2), In-House - In-House Conventional and Real-time PCR (n=1)

**Groups Rolled Up:** AmpliSens - AmpliSens Real Time PCR (n=16), AusDiagnostics - AusDiagnostics Easy-Plex (n=6), Diagenode - Diagenode Real Time kit (n=7), Hologic - Hologic Aptima (n=13), TIB MOLBIOL - TIB-MolBiol LightMix (n=5), fast-track DIAGNOSTICS - FTD real time PCR (n=12)

Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	(n)	(%)	(n)	(%)	(n)
STI_I18S-02	Trichomonas vaginalis	Transport Medium	DS1_1	Trichomonas vaginalis	82.6	95	2.6	3	14.8	17



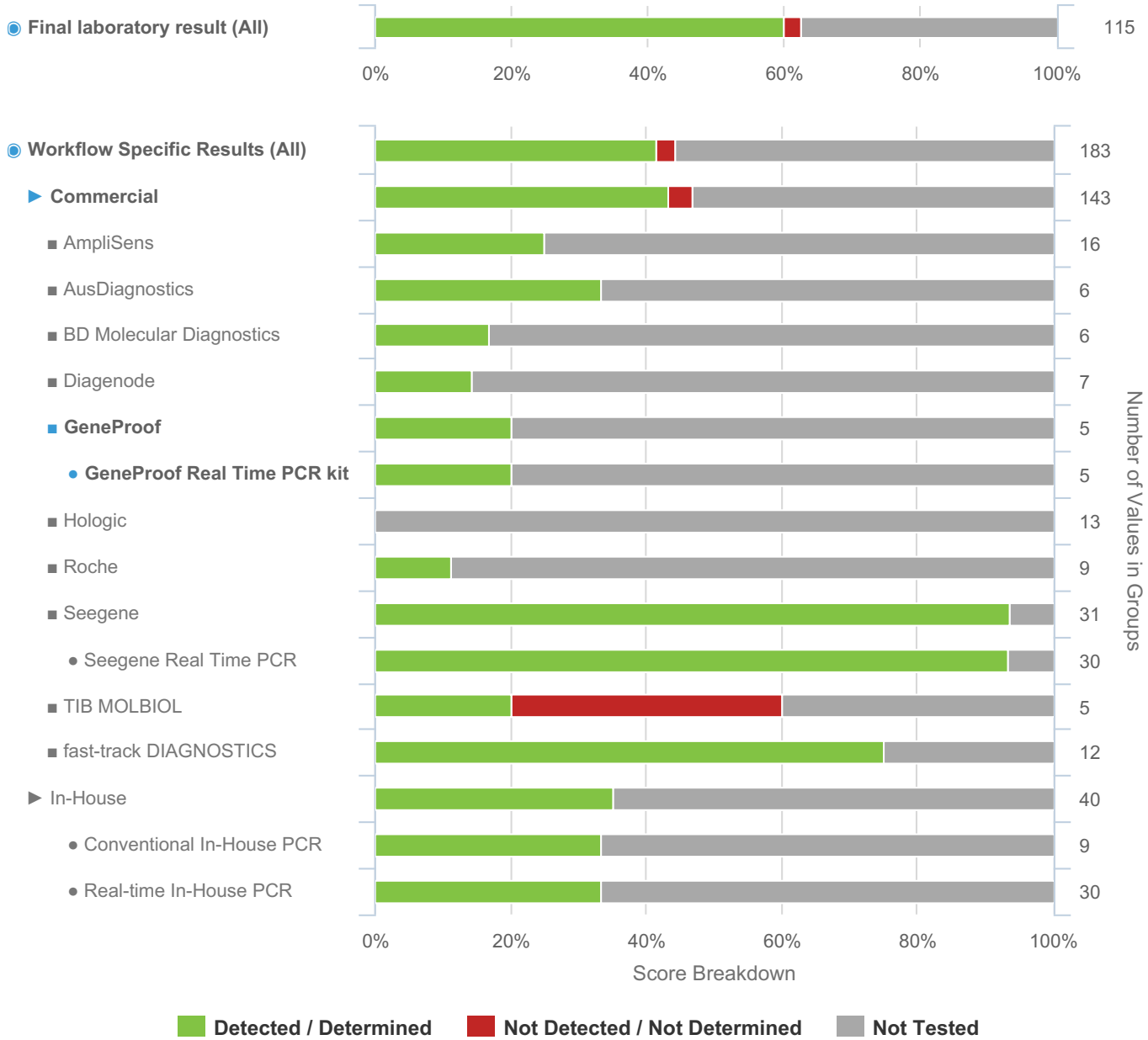


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Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	(n)	(%)	(n)	(%)	(n)
STI_I18S-03	Ureaplasma urealyticum	Transport Medium		Ureaplasma urealyticum	60	69	2.6	3	37.4	43



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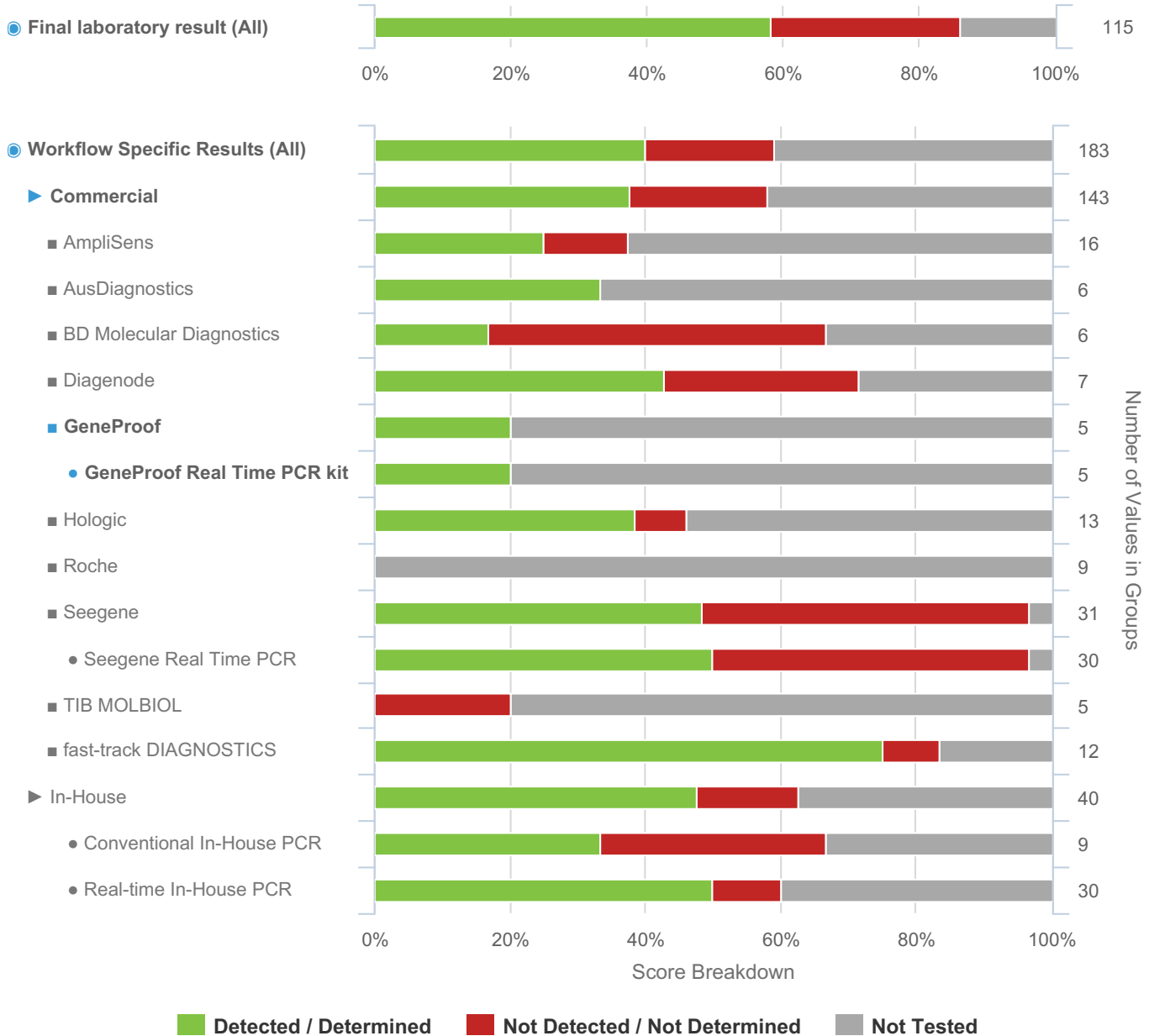


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Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	(n)	(%)	(n)	(%)	(n)
STI_I18S-04	Trichomonas vaginalis	Transport Medium	DS1_3	Trichomonas vaginalis	58.3	67	27.8	32	13.9	16



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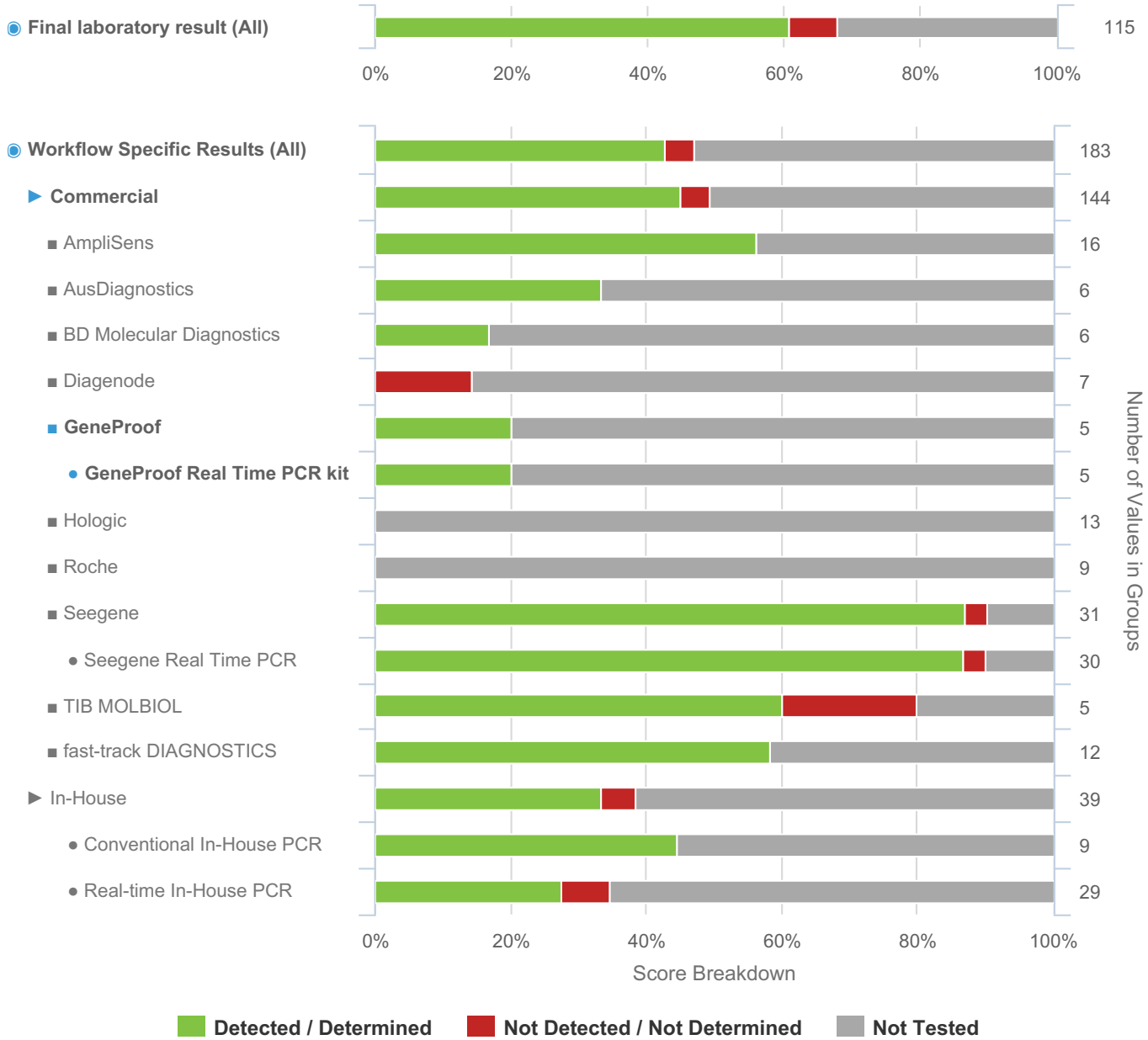


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Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	(n)	(%)	(n)	(%)	(n)
STI_I18S-05	Mycoplasma hominis	Transport Medium		Mycoplasma hominis	60.9	70	7	8	32.2	37



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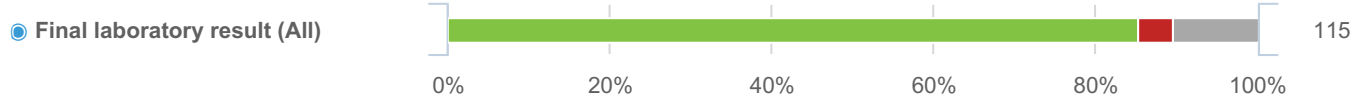
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Catalogue Code: QAB154177	Ref Code: STI_I18	Challenge: S	Analysis Type: Multiple Pathogen Qualitative	Dataset: 256978	Report UID: 2677/16299/1846	Laboratory CZ023
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Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	(n)	(%)	(n)	(%)	(n)
STI_I18S-06	Mycoplasma genitalium (drug resistant)	Transport Medium		Mycoplasma genitalium	85.2	98	4.3	5	10.4	12





# Individual Report

# QCMD 2018 Sexually Transmitted Infections I EQA Pilot Study



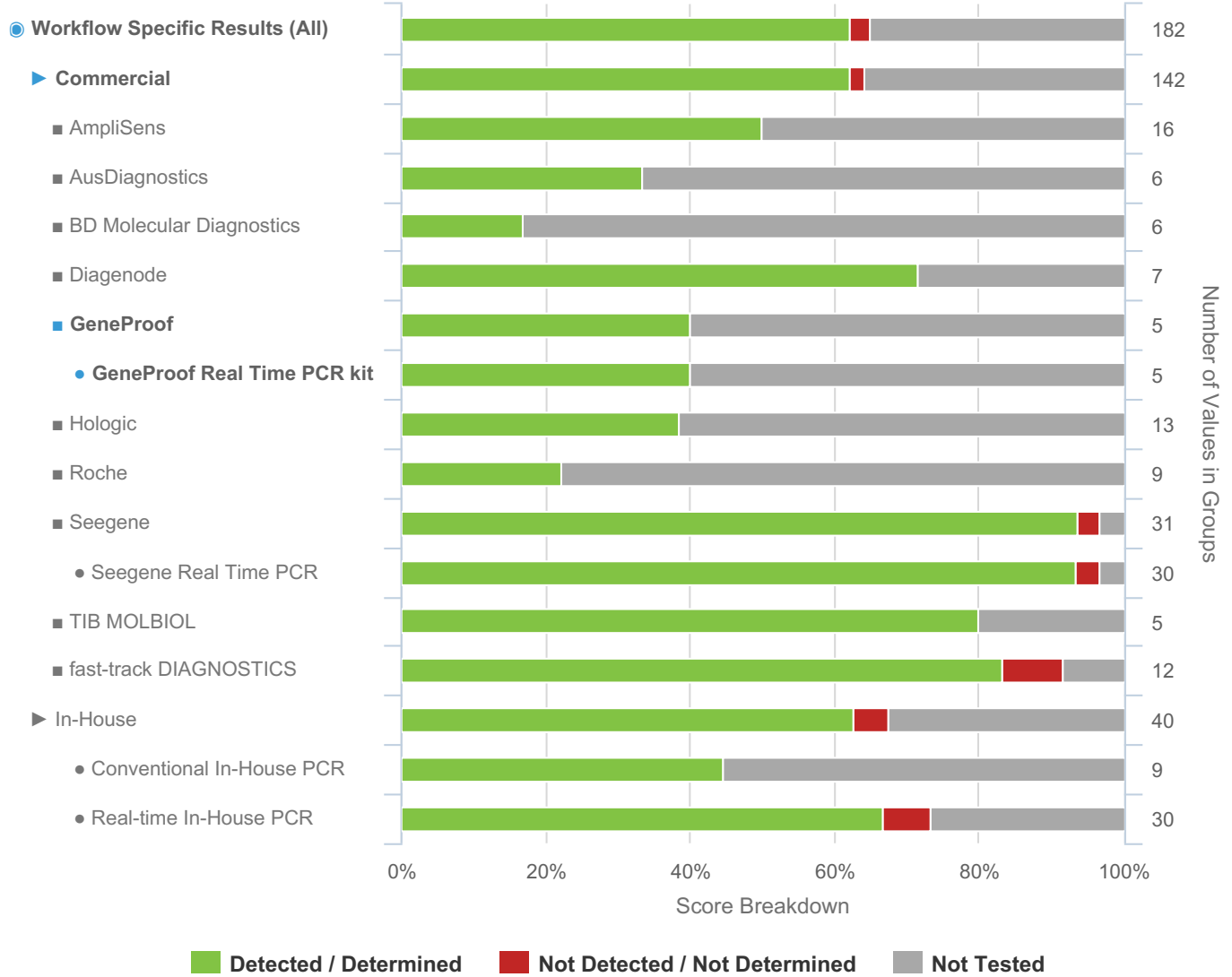
<b>Catalogue Code:</b> QAB154177	<b>Ref Code:</b> STI_I18	<b>Challenge:</b> S	<b>Analysis Type:</b> Multiple Pathogen Qualitative	<b>Dataset:</b> 256978	<b>Report UID:</b> 2677/16299/1846	<b>Laboratory:</b> CZ023
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**Groups below n=5:** AB Analytica (n=4), AB Analytica - AB Analytica REALQUALITY RQ (n=4), Abbott (n=2), Abbott - Abbott Real Time PCR (n=2), Anatolia Geneworks (n=1), Anatolia Geneworks - Anatolia Geneworks Bosphore (n=1), Applied Biosystems (n=1), Applied Biosystems - Applied Biosystems Real Time PCR (n=1), BD Molecular Diagnostics - BD MAX (n=4), BD Molecular Diagnostics - BD ProbeTec (n=2), BIORON (n=3), BIORON - BIORON RealLine (n=3), BioGX (n=2), BioGX - BioGX Sample-Ready (n=2), Cepheid (n=2), Cepheid - Cepheid Xpert kit (n=2), DiagCor (n=1), DiagCor - DiagCor GenoFlow (n=1), Genetic Signatures (n=1), Genetic Signatures - Genetic Signatures Easyscreen (n=1), Hong Kong CH Gene (n=1), Hong Kong CH Gene - HK CH Gene Real Time PCR (n=1), HybriBio (n=1), HybriBio - Multiplex Commercial PCR (n=1), PrimerDesign (n=1), PrimerDesign - PrimerDesign Genesig (n=1), Progenie Molecular (n=1), Progenie Molecular - Progenie Molecular RealCycler (n=1), R-Biopharm (n=4), R-Biopharm - R-Biopharm RIDA Gene (n=4), Randox (n=1), Randox - Randox Multiplex Array (n=1), Roche - Roche Cobas 4800 (n=1), Roche - Roche Cobas 6800/8800 (n=4), Roche - Roche Cobas Amplicor (n=1), Roche - Roche LightCycler (n=3), Sacace (n=4), Sacace - Sacace Real TM (n=4), Seegene - Seegene Seeplex (n=1), SpeeDx (n=2), SpeeDx - SpeeDx Real Time PCR (n=2), In-House - In-House Conventional and Real-time PCR (n=1)

**Groups Rolled Up:** AmpliSens - AmpliSens Real Time PCR (n=16), AusDiagnostics - AusDiagnostics Easy-Plex (n=6), Diagenode - Diagenode Real Time kit (n=7), Hologic - Hologic Aptima (n=13), TIB MOLBIOL - TIB-MolBiol LightMix (n=5), fast-track DIAGNOSTICS - FTD real time PCR (n=12)

<b>Catalogue Code:</b> QAB154177	<b>Ref Code:</b> STI_I18	<b>Challenge:</b> S	<b>Analysis Type:</b> Multiple Pathogen Qualitative	<b>Dataset:</b> 256978	<b>Report UID:</b> 2677/16299/1846	<b>Laboratory:</b> CZ023
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Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	(n)	(%)	(n)	(%)	(n)
STI_I18S-07	Mycoplasma genitalium	Transport Medium		Mycoplasma genitalium	86.1	99	4.3	5	9.6	11

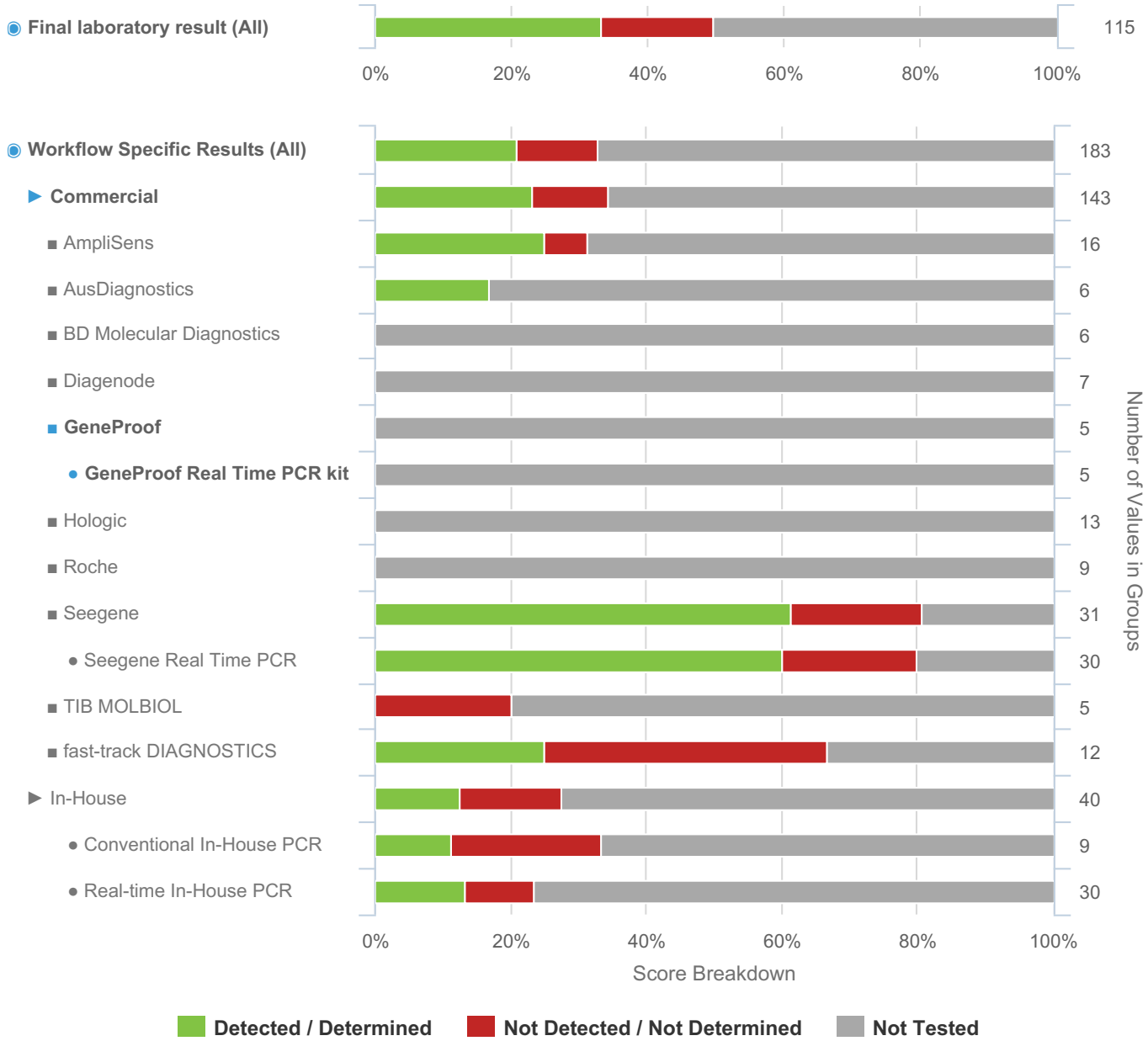



<b>Individual Report</b>		<b>QCMD 2018 Sexually Transmitted Infections I EQA Pilot Study</b>				
<b>Catalogue Code:</b> QAB154177	<b>Ref Code:</b> STI_I18	<b>Challenge:</b> S	<b>Analysis Type:</b> Multiple Pathogen Qualitative	<b>Dataset:</b> 256978	<b>Report UID:</b> 2677/16299/1846	<b>Laboratory</b> CZ023

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Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	(n)	(%)	(n)	(%)	(n)
STI_I18S-08	Chlamydia trachomatis and Mycoplasma hominis	Transport Medium		Mycoplasma hominis and Chlamydia trachomatis	33	38	16.5	19	50.4	58

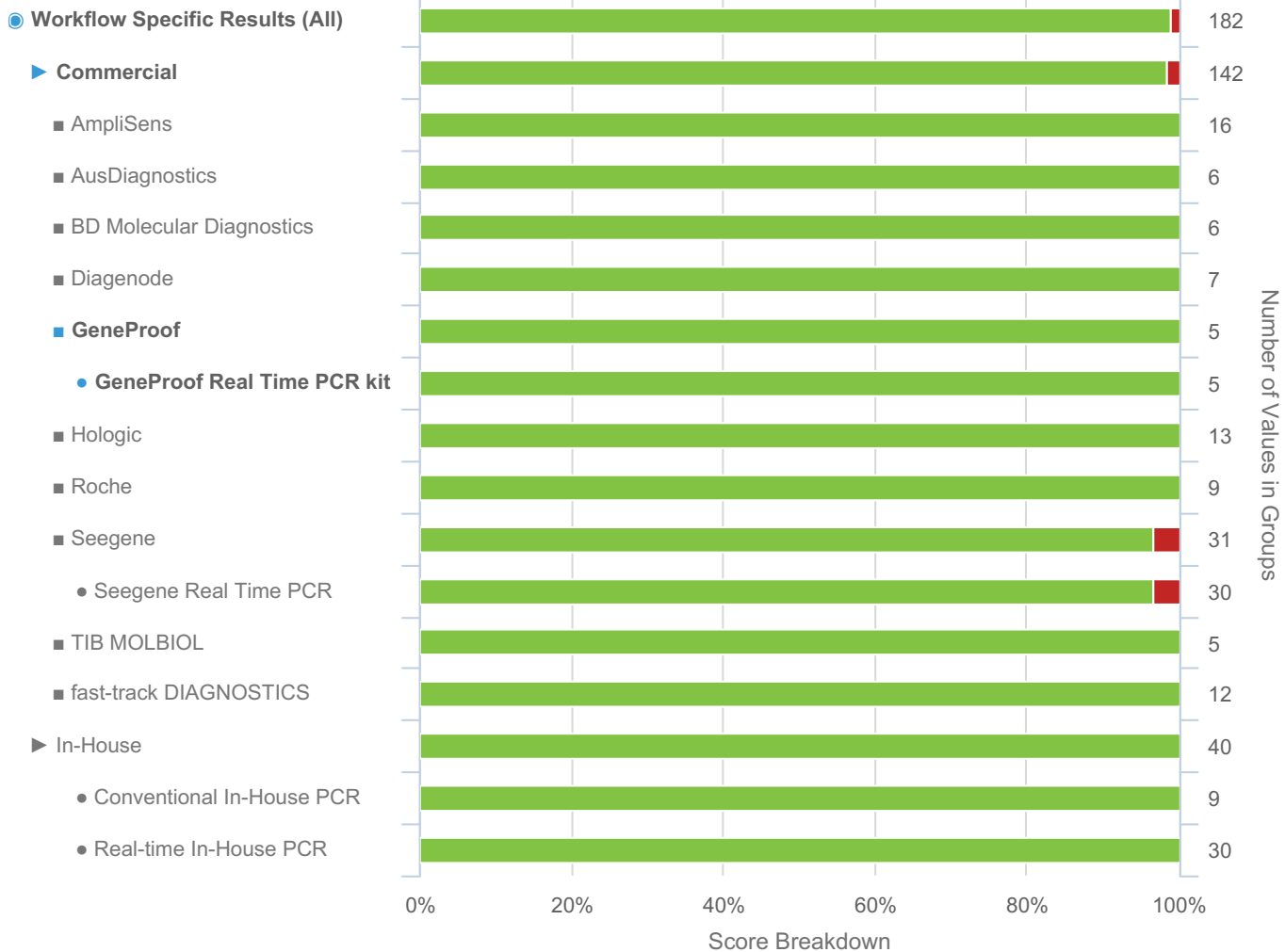


<b>Individual Report</b>		<b>QCMD 2018 Sexually Transmitted Infections I EQA Pilot Study</b>				
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Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	(n)	(%)	(n)	(%)	(n)
STI_I18S-09	Negative	Transport Medium			96.5	111	3.5	4	N/A	0



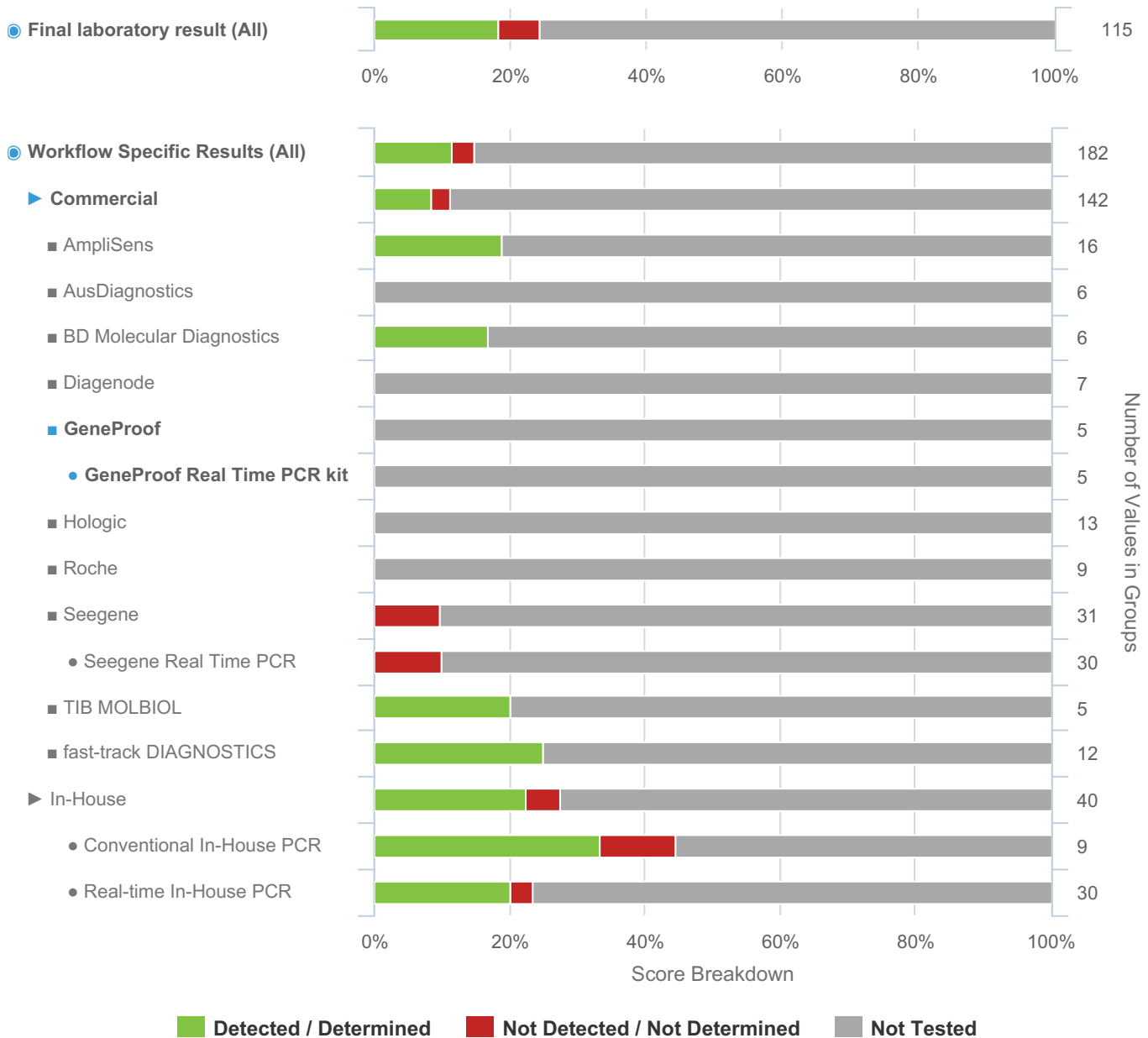
■ Detected / Determined   
 ■ Not Detected / Not Determined   
 ■ Not Tested

<b>Individual Report</b>		<b>QCMD 2018 Sexually Transmitted Infections I EQA Pilot Study</b>				
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Sample Code	Sample Content	Matrix	Sample Relationships	Expected targets	Detected / Determined		Not Detected / Not Determined		Not Tested	
					(%)	(n)	(%)	(n)	(%)	(n)
STI_I18S-10	Gardnerella vaginalis	Transport Medium		Gardnerella vaginalis	18.3	21	6.1	7	75.7	87





# Individual Report

# QCMD 2018 Sexually Transmitted Infections I EQA Pilot Study



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