GXP: Practical Session II

10 July 2019

Results

- GeneXpert Dx software automatically prints out a result

- Results are interpreted by system, from measured fluorescent signals & embedded calculation algorithms

- To see results on monitor:
    1. Click "View Results" icon on toolbar,
    2. Then click "View Test" at bottom of screen
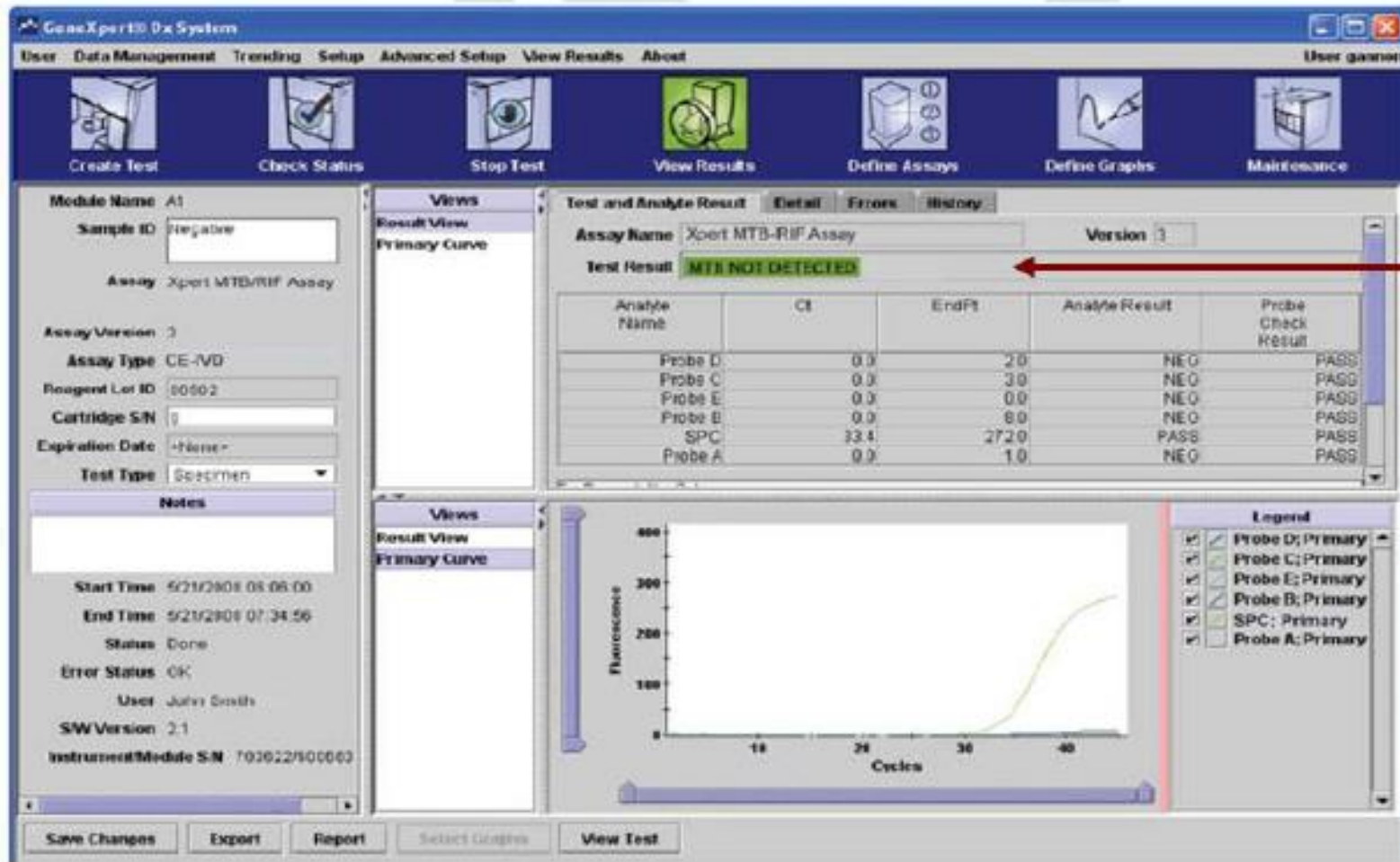   3. Then select sample ID / lab number

▸ Results Window: Positive

▶ Results Window: Negative

MTB NOT DETECTED – No MTB target DNA was detected.

▸ Quality Controls

- Each Xpert MTB/Rif cartridge includes:
  - A Sample processing control (SPC)
  - A Probe Check control (PCC)
- Print out of test result indicates the validation of controls

- Sample Processing Control (SPC):
  - Ensures the sample was correctly processed
  - SPC contains non-infectious spores to verify adequate processing of MTB
  - SPC should be positive in a negative sample and can be negative or positive in a positive sample
  - SPC passes if it meets the validated acceptance criteria
  - Test result will be "Invalid" if the SPC is not detected in a negative test

- Probe Check Control (PCC):
  - Before start of PCR reaction, system measures fluorescence signal from the probes to monitor bead hydration, reaction-tube filling, probe integrity and dye stability
  - Probe Check passes if it meets assigned acceptance criteria

▶ All Possible Xpert Results

MTB Detected	MTB target DNA was detected. The MTB result will be displayed as High, Medium, Low or Very Low depending on the Ct value of the MTB target present in the sample.
	Rif Resistance DETECTED, Rif Resistance NOT DETECTED, or Rif Resistance INDETERMINATE will only be displayed in MTB DETECTED results, on a separate line from the MTB DETECTED result.
Rif Resistance DETECTED	A mutation in the *rpo*B gene, that falls within the valid delta Ct setting has been detected.
Rif Resistance NOT DETECTED	No mutation in the *rpo*B gene has been detected.
Rif Resistance INDETERMINATE	The detected signal was too low and Rif resistance could not be determined.
MTB NOT DETECTED	MTB target DNA was not detected.
INVALID	Presence or absence of MTB target DNA could not be determined, repeat test with extra sample. SPC did not meet acceptance criteria, the sample was not properly processed or PCR was inhibited.
NO RESULT	The presence or absence of MTB target DNA could not be determined due to Probe Check failed or due to insufficient data collected.
ERROR	

▶ Analytical Failures

- Repeat examinations are to be done following analytical failures, using stored residual sediment

COMMON ERROR CODES	EXPLANATION
5006/5007/5008/5009	Incorrect reagent volume: Too little or too viscous
2008/2009	Pressure error due to too viscous sample or blocked filter
INVALID	SPC Control did not amplify
NO RESULT	Manual stop or power interruption
ERROR	Reagent/cartridge error

▶ Interpretation of Results

MTB Detected

MTB Result	Ct Range
High	<16
Medium	16 – 22
Low	22 – 28
Very low	28 – 38

Rifampicin Resistance

Result	Means
Detected	Mutation in *rpoB* gene that falls within delta Ct setting
Not detected	No mutation in *rpoB* gene detected
Indeterminate	MTB concentration very low & resistance could not be detected

Interpretation of Results

MTB Not Detected
- MTB target DNA is not detected
- SPC meets acceptance criteria - SPC has a Ct value range & endpoint above minimum setting
- All probe check results pass

RIF Not Detected
- Rifampicin target DNA is not detected
- SPC meets acceptance criteria - SPC has a Ct value range & endpoint above minimum setting
- All probe check results pass

Invalid
- Presence / absence of MTB cannot be determined
  - Repeat test with extra specimen
- SPC does not meet acceptance criteria, the sample was not properly processed, or PCR is inhibited
- All probe check results pass

▶ Limitations of Assay

- Reliable results depend on proper specimen collection, handling, & storage

- A positive test result does not necessarily indicate presence of viable organisms; it is presumptive for presence of MTB & rifampicin resistance

- Results might be affected by previous or current anti-TB drug therapy

- Results cannot be used to assess treatment response

Test Report

Patient ID:
Sample ID:　　　　　▓▓▓▓▓▓▓▓
Test Type:　　　　　Specimen
Sample Type:

Assay Information

Assay	Assay Version	Assay Type
Xpert MTB-RIF G3	3	In Vitro Diagnostic

Test Result:　　**MTB DETECTED HIGH;**
Rif Resistance DETECTED

Test and Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
Probe D	13.0	250.0	POS	PASS
Probe C	12.5	246.0	POS	PASS
Probe E	0	-6.0	NEG	PASS
Probe B	12.6	189.0	POS	PASS
SPC	26.7	284.0	NA	PASS
Probe A	12.0	125.0	POS	PASS

User:　　　　　　　　▓▓▓▓▓▓
Status:　　　　　　　Done　　　　　　　Start Time:　　　　16/03/11 09:36:04
Reagent Lot ID*:　　02101　　　　　　End Time:　　　　　16/03/11 11:23:36
Expiration Date*:　　02/10/11　　　　Module Name:　　　A3
Cartridge S/N*:　　　29484912　　　　Module S/N:　　　　602364
S/W Version:　　　　2.1　　　　　　　Instrument S/N:　　702403
Notes:
Error Status:　　　　OK

Errors

<None>

Error Status:　　　　OK

Errors
<None>

_____　_____
Tech. Initial/Date　　　　　　　　Supervisor Initial/Date
* indicates that a particular field is entered using a barcode scanner

For In Vitro Diagnostics Use Only.

For In Vitro Diagnostic Use Only.

Test Report

Patient ID:
Sample ID:
Test Type: Specimen
Sample Type:

Assay Information

Assay	Assay Version	Assay Type
Xpert MTB-RIF Assay G4	5	In Vitro Diagnostic

Test Result: MTB DETECTED HIGH;
Rif Resistance NOT DETECTED

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
Probe D	16.2	231	POS	PASS
Probe C	15.0	247	POS	PASS
Probe E	16.8	125	POS	PASS
Probe B	16.1	138	POS	PASS
SPC	24.9	250	NA	PASS
Probe A	14.6	158	POS	PASS
QC-1	0.0	0	NEG	PASS
QC-2	0.0	0	NEG	PASS

User:
Status: Done
Expiration Date*: 28/01/18
S/W Version: 4.4a
Cartridge S/N*: 258685011
Reagent Lot ID*: 33422
Notes:

Start Time: 08/11/16 15:07:02
End Time: 08/11/16 16:46:34
Instrument S/N: 702403
Module S/N: 612966
Module Name: A1

Error Status: OK

Errors
<None>

_____   _____
Tech. Initial/Date   Supervisor Initial/Date
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Test Report

Patient ID:
Sample ID:
Test Type: Specimen
Sample Type:

Assay Information

Assay	Assay Version	Assay Type
Xpert MTB-RIF Assay G4	5	In Vitro Diagnostic

Test Result: MTB DETECTED MEDIUM;
Rif Resistance NOT DETECTED

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
Probe D	18.9	213	POS	PASS
Probe C	18.1	235	POS	PASS
Probe E	19.8	122	POS	PASS
Probe B	18.8	139	POS	PASS
SPC	24.8	289	NA	PASS
Probe A	17.7	132	POS	PASS
QC-1	0.0	0	NEG	PASS
QC-2	0.0	0	NEG	PASS

User:
Status: Done   Start Time: 17/11/16 09:10:42
Expiration Date*:   07/05/17   End Time: 17/11/16 10:50:31
S/W Version: 4.4a   Instrument S/N: 702403
Cartridge S/N*:   260503771   Module S/N: 619058
Reagent Lot ID*:   33906   Module Name: A3
Notes:

OK

<None>

_____   _____
Tech. Initial/Date   Supervisor Initial/Date
* indicates that a particular field is entered using a barcode scanner

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Test Report

Patient ID:
Sample ID:
Test Type: Specimen
Sample Type:

Assay Information

Assay	Assay Version	Assay Type
Xpert MTB-RIF Assay G4	5	In Vitro Diagnostic

Test Result: **MTB DETECTED LOW;**
Rif Resistance NOT DETECTED

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
Probe D	25.3	170	POS	PASS
Probe C	24.8	179	POS	PASS
Probe E	26.5	158	POS	PASS
Probe B	25.0	146	POS	PASS
SPC	24.0	295	NA	PASS
Probe A	24.6	138	POS	PASS
QC-1	0.0	0	NEG	PASS
QC-2	0.0	0	NEG	PASS

User:

Status:	Done	Start Time:	02/02/17 15:03:32
Expiration Date*:	07/05/17	End Time:	02/02/17 16:43:24
S/W Version:	4.4a	Instrument S/N:	706423
Cartridge S/N*:	260504317	Module S/N:	613195
Reagent Lot ID*:	33906	Module Name:	B3
Notes:			

Error Status: OK

Errors
<None>

_____   _____
Tech. Initial/Date   Supervisor Initial/Date
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Test Report

Patient ID:
Sample ID:
Test Type: Specimen
Sample Type:

Assay Information

Assay	Assay Version	Assay Type
Xpert MTB-RIF Assay G4	5	In Vitro Diagnostic

Test Result: **MTB DETECTED VERY LOW;**
                  Rif Resistance NOT DETECTED

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
Probe D	29.8	116	POS	PASS
Probe C	28.8	140	POS	PASS
Probe E	30.8	105	POS	PASS
Probe B	29.2	111	POS	PASS
SPC	28.4	254	NA	PASS
Probe A	28.7	111	POS	PASS
QC-1	0.0	0	NEG	PASS
QC-2	0.0	0	NEG	PASS

User:

Status:	Done	Start Time:	18/01/17 11:49:09	Error Status: OK
Expiration Date*:	07/05/17	End Time:	18/01/17 13:28:57	
S/W Version:	4.4a	Instrument S/N:	706423	Errors
Cartridge S/N*:	260504579	Module S/N:	624394	<None>
Reagent Lot ID*:	33906	Module Name:	B2	

Notes:

_____   _____

       Tech. Initial/Date   Supervisor Initial/Date

* indicates that a particular field is entered using a barcode scanner

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Test Report

Patient ID:
Sample ID:
Test Type: Specimen
Sample Type:

Assay Information

Assay	Assay Version	Assay Type
Xpert MTB-RIF Assay G4	5	In Vitro Diagnostic

Test Result: **MTB DETECTED VERY LOW;**
Rif Resistance INDETERMINATE

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
Probe D	34.6	68	POS	PASS
Probe C	33.4	95	POS	PASS
Probe E	36.4	54	NEG	PASS
Probe B	33.1	82	POS	PASS
SPC	24.9	244	NA	PASS
Probe A	34.3	69	POS	PASS
QC-1	0.0	0	NEG	PASS
QC-2	0.0	0	NEG	PASS

User:
Status: Done
Expiration Date: <None>
S/W Version: 4.7b
Cartridge S/N: 0
Reagent Lot ID: 33906
Notes:

Start Time: 19/05/17 15:23:13
End Time: 19/05/17 17:02:53
Instrument S/N: 702403
Module S/N: 612966
Module Name: A1

Error Status: OK

Errors
<None>

_____   _____
     Tech. Initial/Date   Supervisor Initial/Date
* indicates that a particular field is entered using a barcode scanner

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Test Report

Patient ID:
Sample ID:
Test Type: Specimen
Sample Type:

Assay Information

Assay	Assay Version	Assay Type
Xpert MTB-RIF Assay G4	5	In Vitro Diagnostic

Test Result: **MTB DETECTED VERY LOW; Rif Resistance DETECTED**

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
Probe D	31.8	103	POS	PASS
Probe C	31.6	92	POS	PASS
Probe E	33.7	80	POS	PASS
Probe B	0.0	4	NEG	PASS
SPC	22.7	243	NA	PASS
Probe A	31.6	80	POS	PASS
QC-1	0.0	0	NEG	PASS
QC-2	0.0	0	NEG	PASS

User:			
Status:	Done	Start Time:	17/11/16 12:37:13
Expiration Date*:	07/05/17	End Time:	17/11/16 14:17:08
S/W Version:	4.4a	Instrument S/N:	702403
Cartridge S/N*:	260503773	Module S/N:	619058
Reagent Lot ID*:	33906	Module Name:	A3
Notes:			

Error Status: OK

Errors
<None>

_____   _____
Tech. Initial/Date   Supervisor Initial/Date
* indicates that a particular field is entered using a barcode scanner

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Patient ID:
Sample ID:
Test Type: Specimen
Sample Type:

Assay Information

Assay	Assay Version	Assay Type
Xpert MTB-RIF Assay G4	5	In Vitro Diagnostic

Test Result: **MTB NOT DETECTED**

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
Probe D	0.0	-2	NEG	PASS
Probe C	0.0	-2	NEG	PASS
Probe E	0.0	-7	NEG	PASS
Probe B	0.0	-1	NEG	PASS
SPC	23.3	245	PASS	PASS
Probe A	0.0	1	NEG	PASS
QC-1	0.0	0	NEG	PASS
QC-2	0.0	0	NEG	PASS

User:
Status: Done   Start Time: 18/11/16 12:48:28
Expiration Date*: 07/05/17   End Time: 18/11/16 14:28:18
S/W Version: 4.4a   Instrument S/N: 702403
Cartridge S/N*:   260504018   Module S/N: 619058
Reagent Lot ID*:   33906   Module Name: A3
Notes:
Error Status: OK

Errors
<None>

TASK GX4's 702403 & 706423 TASK LABORATORY PAROW   13/03/19 11:11:20

Test Report

_____   _____
Tech. Initial/Date   Supervisor Initial/Date
* indicates that a particular field is entered using a barcode scanner

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Test Report

Patient ID:

Sample ID:

Test Type: Specimen

Sample Type:

Assay Information

Assay	Assay Version	Assay Type
Xpert MTB-RIF Assay G4	5	In Vitro Diagnostic

Test Result: NO RESULT

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
Probe D	0.0	0	NO RESULT	NA
Probe C	0.0	0	NO RESULT	NA
Probe E	0.0	0	NO RESULT	NA
Probe B	0.0	0	NO RESULT	NA
SPC	0.0	0	NO RESULT	NA
Probe A	0.0	0	NO RESULT	NA
QC-1	0.0	0	NO RESULT	NA
QC-2	0.0	0	NO RESULT	NA

User:			
Status:	Aborted	Start Time:	06/03/17 16:33:04
Expiration Date*:	07/05/17	End Time:	06/03/17 16:33:07
S/W Version:	4.4a	Instrument S/N:	706423
Cartridge S/N*:	260504223	Module S/N:	624394
Reagent Lot ID*:	33906	Module Name:	B2
Notes:			
Error Status:	Load Error		

Errors

#	Description	Detail	Time
1	Post-run analysis error	Error 5006: [Probe A] probe check failed. Probe check value of 329 for reading number 1 was above the maximum of 214	05/04/17 15:17:07
2	Post-run analysis error	Error 5006: [Probe A] probe check failed. Probe check value of 329 for reading number 3 was above the maximum of 214	05/04/17 15:17:07
3	Post-run analysis error	Error 5006: [Probe D] probe check failed. Probe check value of 476 for reading number 1 was above the maximum of 177	05/04/17 15:17:07
4	Post-run analysis error	Error 5006: [Probe D] probe check failed. Probe check value of 487 for reading number 3 was above the maximum of 177	05/04/17 15:17:07
5	Post-run analysis error	Error 5006: [Probe C] probe check failed. Probe check value of 716 for reading number 1 was above the maximum of 288	05/04/17 15:17:07
6	Post-run analysis error	Error 5006: [Probe C] probe check failed. Probe check value of 725 for reading number 3 was above the maximum of 288	05/04/17 15:17:07
7	Post-run analysis error	Error 5006: [Probe E] probe check failed. Probe check value of 1351 for reading number 1 was above the maximum of 160	05/04/17 15:17:07
8	Post-run analysis error	Error 5006: [Probe E] probe check failed. Probe check value of 1406 for reading number 3 was above the maximum of 160	05/04/17 15:17:07
9	Post-run analysis error	Error 5007: [Probe B] probe check failed. Probe check value of 75 for reading number 2 was below the minimum of 78	05/04/17 15:17:07
10	Post-run analysis error	Error 5007: [SPC] probe check failed. Probe check value of 139 for reading number 2 was below the minimum of 188	05/04/17 15:17:07

Test Report

Patient ID:
Sample ID:
Test Type: Specimen
Sample Type:

Assay Information

Assay	Assay Version	Assay Type
Xpert MTB-RIF Assay G4	5	In Vitro Diagnostic

Test Result: **ERROR**

Analyte Result

Analyte Name	Ct	EndPt	Analyte Result	Probe Check Result
Probe D	0.0	0	NO RESULT	FAIL
Probe C	0.0	0	NO RESULT	FAIL
Probe E	0.0	0	NO RESULT	FAIL
Probe B	0.0	0	NO RESULT	FAIL
SPC	0.0	0	NO RESULT	FAIL
Probe A	0.0	0	NO RESULT	FAIL
QC-1	0.0	0	NO RESULT	PASS
QC-2	0.0	0	NO RESULT	PASS

User:			
Status:	Aborted	Start Time:	05/04/17 14:30:27
Expiration Date*:	07/05/17	End Time:	05/04/17 15:17:34
S/W Version:	4.4a	Instrument S/N:	702403
Cartridge S/N*:	260503733	Module S/N:	618780
Reagent Lot ID*:	33906	Module Name:	A4
Notes:			
Error Status:	Error		

Errors

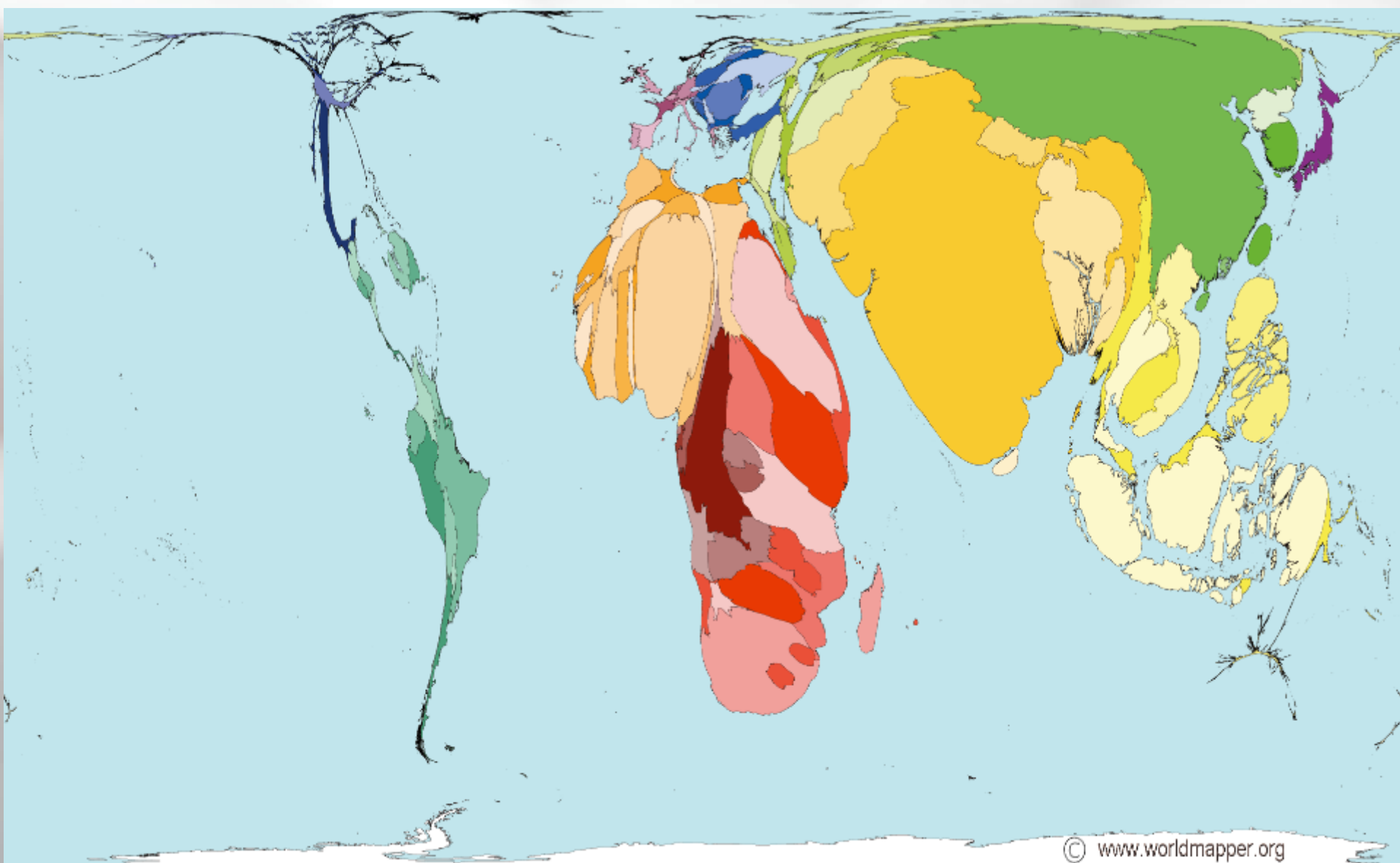| #	Description	Detail	Time
1	Error occurred	Error 4014: The optical signal from Detector 4/LED 0 did not reach the expected value. Expected value=2000, Actual value=7	06/03/17 16:33:06

_____   _____
Tech. Initial/Date   Supervisor Initial/Date

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THANK YOU

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