



building towards

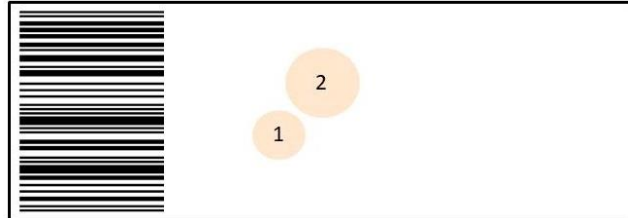
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CIQC

**Summary report for CIQC Run 80:**

**June 1<sup>st</sup> 2018**

- Run 80 consists of 2 FFPE samples for HER2 ISH (FISH, CISH, SISH).
- For orientation purposes, Sample 1 is a 1-mm core and Sample 2 is a 2-mm core.



- Provide the average number of signals per nucleus for HER2 and CEP17, as well as report the samples to be either
  - *Amplified*
  - *Non-Amplified*
  - *Equivocal*
  - *Unsatisfactory for analysis*
- Enter ISH results as Non-amplified (N), Equivocal (E) or Amplified (A)
  - <1.8 (non-amplified)
  - 1.8 – 2.2 (equivocal)
  - >2.2 (amplified)
- Samples used in this block have been formalin-fixed and processed through alcohol and xylene into paraffin wax in the usual manner. If you do not use the same tissue processing in your laboratory, the results obtained with this test may or may not be representative of your laboratory performance.

Results were received from 14 participants and summarized below.



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### Run 80 Interpretation

Laboratories/ Cores	102	107	109	111	114	115	125	137	138	175	181	194	202	217	R1
1	N	N	E	E	E	E	N	E	E	N	E	A	E	E	Amp
2	U	U	U	N	N	N	U	N	N	U	U	N	N	U	Non-amp

### Run 80 Signal Counts

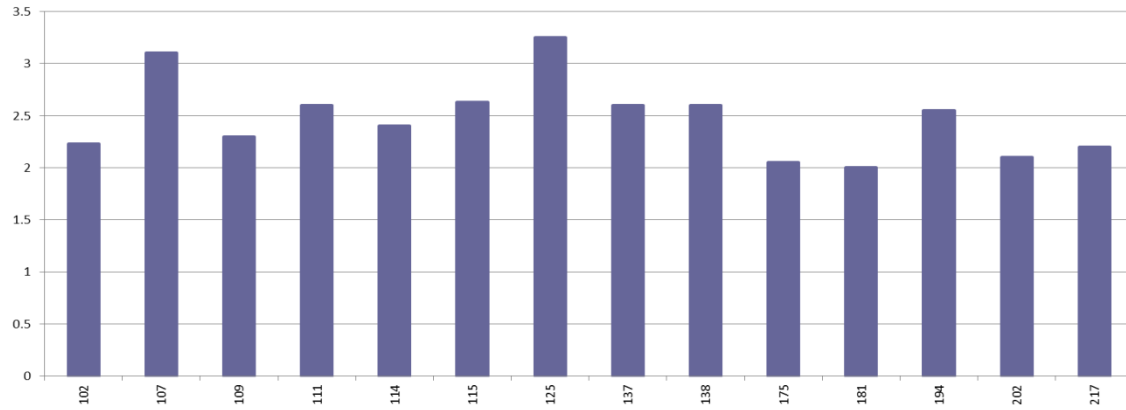
Laboratories/Fields	102	107	109	111	114	115	125	137	138	175	181	194	202	217
Sample 1 - Avg # Cep17 signals	2.23	3.1	2.3	2.6	2.4	2.63	3.25	2.6	2.6	2.05	2	2.55	2.1	2.2
Sample 1 - Avg # HER2 signals	3.53	5.29	4.4	5.4	4.4	4.92	4.35	5.5	4.9	3.15	4.4	5.72	4.4	4.1
Sample 1 HER2/CEP17 ratio	1.58	1.71	1.9	2.1	1.8	1.87	1.34	2.1	1.9	1.5	2.2	2.24	2.1	1.9
Sample 2 - Avg # Cep17 signals	Unsatisfactory	Fail	N/A	2.8	3.1	2.33	unsat	2.8	1.8	unsat	n/a	2.79	1.7	N/A
Sample 2 - Avg # HER2 signals	Unsatisfactory	Fail	N/A	2.5	2.7	2.88	unsat	2.8	2	unsat	n/a	3.12	1.7	N/A
Sample 2 HER2/CEP17 ratio	Unsatisfactory	Fail	N/A	0.89	0.9	1.24	unsat	1	1.1	unsat	n/a	1.12	1	N/A



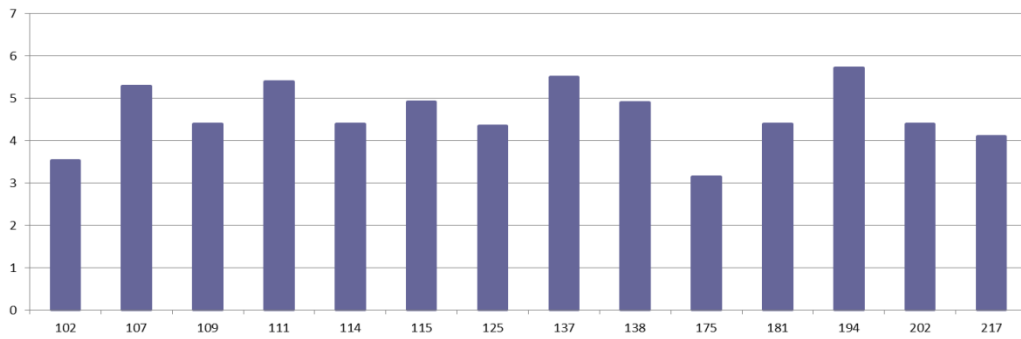
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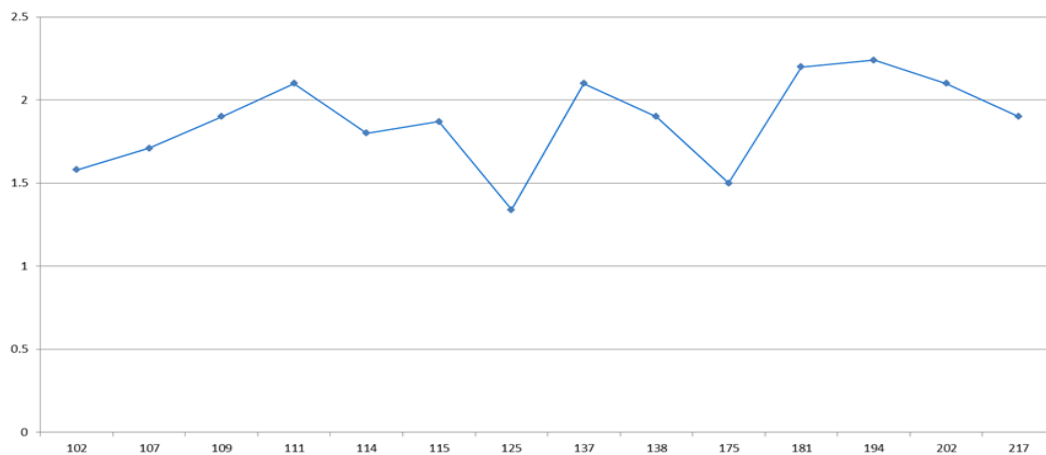
Sample 1 - Avg # Cep17 signals



Sample 1 - Avg # HER2 signals



Sample 1 HER2/CEP17 ratio

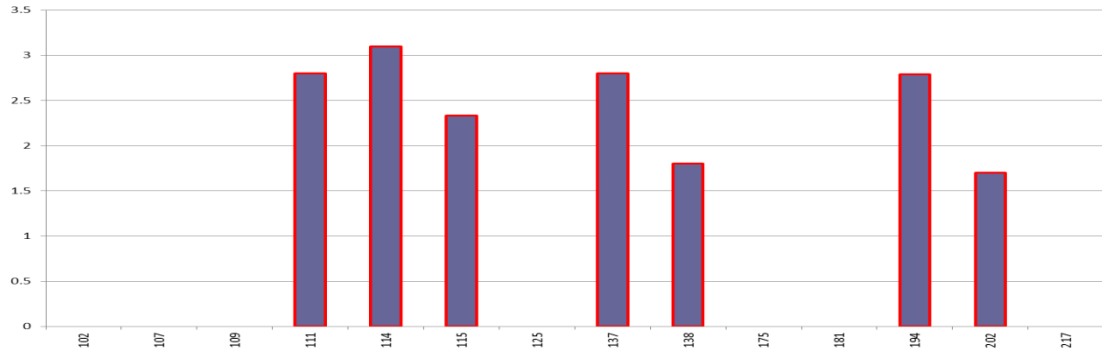




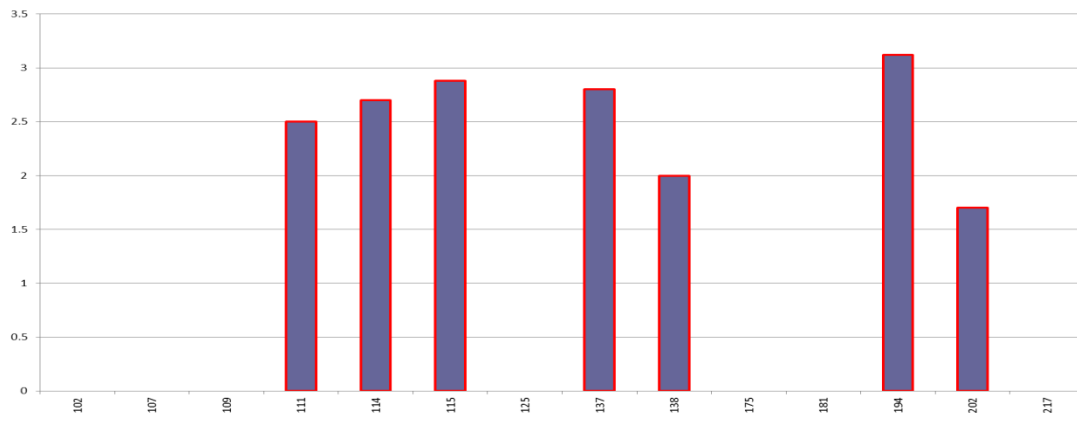
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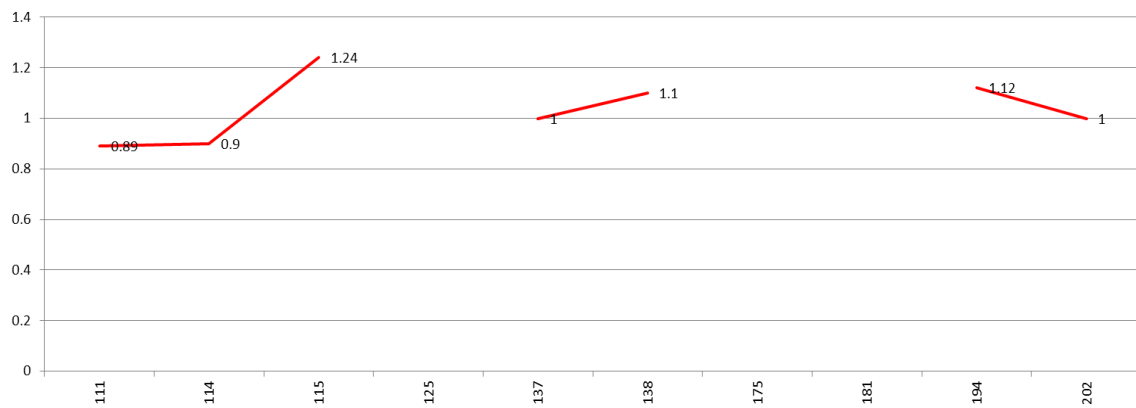
Sample 2 - Avg # Cep17 signals



Sample 2 - Avg # HER2 signals



Sample 2 HER2/CEP17 ratio





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## Run 80 Protocols

Laboratories/Fields	102	107	109	111	114	115	125	137	138	175	181	194	202	217
Supplier/Vendor	Ventana (Roche)	PathVysion	ROCHE	Intermedico	Vysis	Intermedico	Ventana	Abbott/Vysis	Dako	Roche	Ventana/Roche	Abbott	Abbott	Roche Ventana
Probe	Inform Her2 Dual ISH DNA Probe	HER-2 DNA Probe Kit II	HER2/CHR 17	PathVysion HER2	Her2/Cep17	HER2/CEP17	not provided	Pathvysion	Her2 IQ FISH pharmDx	Inform HER2 Dual ISH DNA probe cocktail	Inform Her2 Dual ISH DNA probe CKTL	Pathvission Her-2 DNA Probe Kit	Her2 DNA probe	HER2/C17 dual BRISH
Instrument	Ventana Benchmark XT	NA	BENCHMARK ULTRA	VP 2000	Vysis HYbrite	Hybridizer	benchmark	Thermobrite	Dako Omnis	BenchmarkUltra	Ventana BenchMark	Thermobrite	Hybridizer	Ventana Benchmark Ultra
If manual protocol, specify method (use N/A if not manual)	NA	Paraffin FISH	N/A	na	Manua1	FISH	not provided	In house	N/A	N/A	N/A	NA	n/a	N/A
Denaturation time/temp	20"/80	75oC/5min	8 MIN	5 min/ 73C	5min/73C	2 mins @ 73 degrees	not provided	74c 5min	10 min/66	8 minutes/80 degrees	20 minutes at 80 Deg.C	5min/74C	5min/73C	16min
Hybridization time/temp	360"/44	37oC 16-18hrs (overnight)	6 HOURS	16 hrs/ 37C	16hrs/37C	15 hours @ 37 degrees	not provided	37c overnight	1:15h /45	6 hours/72 degrees	6 hours at 44 Deg.C	24hrs/37C	18 hrs/37C	360min
Pre-treatment reagent/time/temp	CC2 32"/90	2XSSC/3min/room temp	CC2 12 MIN AT 82 DEGREES	10 mM Na citrate/ 100 min/ 80C	40min/95C, then 20min cooled to room temp	1M NaScN / 40 mins/ 80 degrees	not provided	Sodium citrate 80c 2 hours	Dako Omnis Pre-Treatment Solution/20 min/97	CC2/62 minutes/80 degrees	CC2 for 48 minutes at 90 Deg.C	Sodium Citrate 2hrs/80C	30min/80C	UltraCC2/120min/100C
Proteolytic digestion reagent/time/temp	ISH Protease 3 8"/37	Pepsin/13min/37oC	ISH PROTEASE 3 20 MIN	pepsin/ 20 min/ 37C	250ug/mL Pepsin in 0.2N HCL/25min/RT	pepsin/ 20 mins/ @ 37 degrees	not provided	pepsin 37c 15min	Dako Omnis Pepsin/20 min	protease3/20 minutes/80 degrees	Protease3 for 4 minutes at 37 Deg.C	pepsin 20min/37C	5 min/124C	ISH protease
Post-hybridization wash time/temp	8"/72	2min/73oC	16 MIN AT 72 DEGREES	2 min/ 72C	2min/73C	8 mins@ RT & 8 mins @ 72 degrees	not provided	72c 2min, room temp 1min	10 min/61	72 degrees	SSC for 16 minutes at 72 Deg.C	2min/72C	2 min/RT	24min/74C