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CIQC

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Summary report for CIQC Run 40: HER2 ISH

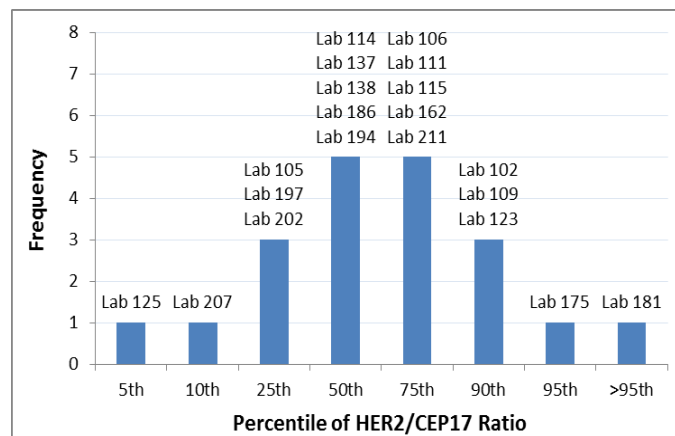
Run 40 consisted of two FFPE cell line samples (one non-amplified and one amplified) for HER2 ISH (FISH, CISH, SISH) on a single slide. Laboratories were requested to stain the slide as per their usual protocol.

Each participant was asked to provide the average number of signals per nucleus (HER2 and CEP17) and report final ISH results online as Non-amplified, Equivocal or Amplified according to the following HER2/CEP17 ratio categories:

- <1.8 = Non-amplified (N)
- 1.8 – 2.2 = Equivocal (E)
- >2.2 = Amplified (A)

Slides were sent to 25 labs and results were received from 22 participants as summarized below. Data from Lab 116 has not been included in the results section of this report as quantitative results were not reported.

Lab ID	102	105	106	109	111	114	115	123	125	137	138	162	175	181	186	194	197	202	207	211
HER2/CEP17 Ratio Sample 1	1.33	1	1.24	1.13	1.25	1.07	1.2	1.34	1.05	1.03	1.24	1.18	1.11	1.36	1.13	1.03	1.11	1.04	1.05	1.08
HER2/CEP17 Ratio Sample 2	5.35	3.44	4.86	5.16	4.69	4.23	4.51	5.27	2.53	3.54	4.39	4.75	7.13	7.63	4.24	4.13	3.15	3	2.89	4.76





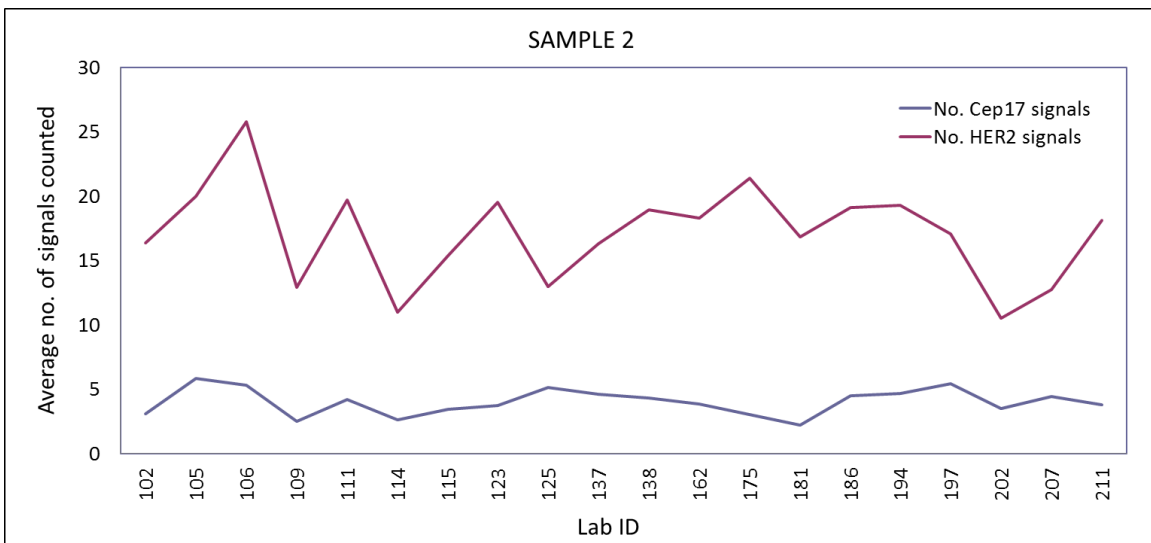
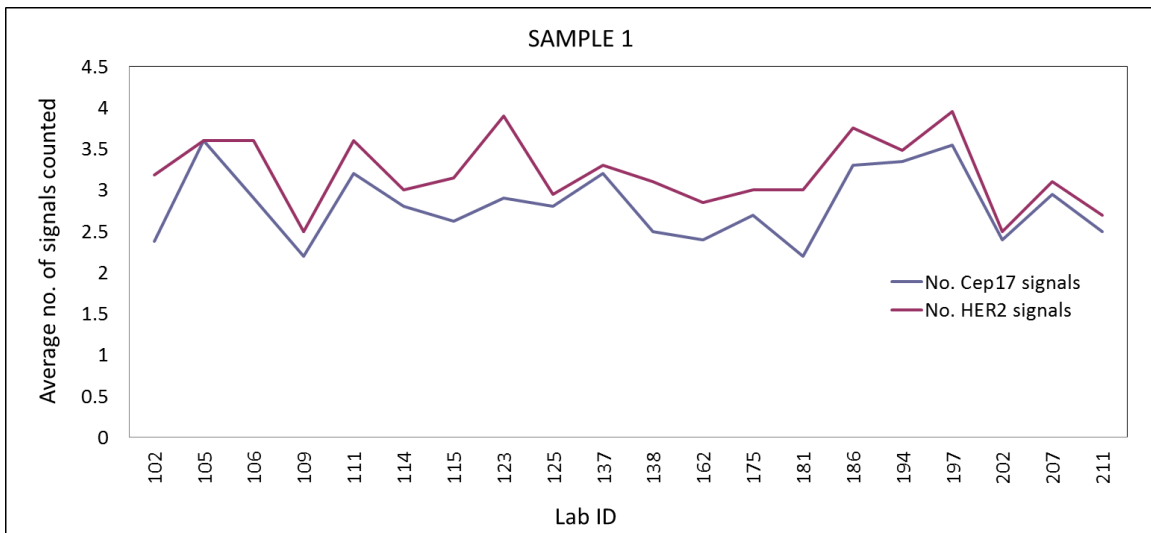
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Individual number of HER2 and CEP17 signals reported:

Lab ID	102	105	106	109	111	114	115	123	125	137	138	162	175	181	186	194	197	202	207	211
No. Cep17 signals Sample 1	2.38	3.6	2.9	2.2	3.2	2.8	2.62	2.9	2.8	3.2	2.5	2.4	2.7	2.2	3.3	3.35	3.55	2.4	2.95	2.5
No. HER2 signals Sample 1	3.18	3.6	3.6	2.5	3.6	3	3.15	3.9	2.95	3.3	3.1	2.85	3	3	3.75	3.48	3.95	2.5	3.1	2.7
No. Cep17 signals Sample 2	3.05	5.8	5.3	2.5	4.2	2.6	3.4	3.7	5.1	4.6	4.3	3.85	3	2.2	4.5	4.65	5.4	3.5	4.4	3.8
No. HER2 signals Sample 2	16.33	20	25.8	12.9	19.7	11	15.3	19.5	13	16.3	18.9	18.3	21.4	16.8	19.1	19.3	17.1	10.5	12.8	18.1





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Staining Protocols:

Lab ID	Probe	Vendor	Instrument	Hybridization Time	Pretreatment Time	Post Hybridization Wash: Reagent, Temp, Time
102	Infrom HER2 Dual ISH Probe Cocktail	Roche	Benchmark XT	6 hours	8 minutes	SSC 72 degrees, 8"
105	Pathvysion HER2	Vysis	Manual	16-18 hrs	50 mins	2x SSC / 0.3% NP40, 72C, 2 mins
106	PathVysion	Vysis/Abbott	ThermoBrite	18 hours	3 hours	0.3% NP40 in 2XSSC at 75C for 6 minutes
109	INFORM HER2 DUAL ISH	VENTANA	BENCHMARK ULTRA	6 hours	12 minutes	SSC @72 degrees for 24 min(3-8min washes
111	PathVysion Her-2 kit	Intermedico	VP2000	16 hours	100 minutes	2xSSC/0.3% NP-40, 72C, 2 min
114	Her-2/Cep-17	Vysis PathVysion	Vysis Hybrite	16 hours	60 min	Buffer, 73C, 2 min
115	Her2-DNA Probe Vysis LSI Her2/neu Cep17	Path Vysion	Thermobrite	15 hours	40 min	2x ssc/0.3%NP40, 72 degrees (celcius), 8min
116	LSI her-2/neu SO/CEP 17 SG Probe	Pathvision	Hybridizer DAKO	24 hres	20 min	NP-40 0.3 %, 72 Â°C, 4 min
123	PathVysion	Abbott	Hybrite	overnight	15	0.4XSSC/0.3%NP40,71.5,2min
125	Roche HER2 DNA probe	Roche	Ventana Ultra	6 hours	protease, 8 min	3 X SSC, 8 min each
137	Pathvysion	Abbott Molecular	Thermobrite	overnight	2hr/15min	2xSSC/0.3%NP40 for 2min @73c, 2xSSC/0.3%NP40 for 30sec at room temp.
138	Dako pharmDx HER2/CEN-17 Probe Mix	Dako	Dako Hybridizer	20 hours	10 minutes	Stringent wash, 65C, 10 minutes
162	Zytolight SPEC HER2/CEN17	Zytovision	Thermobrite	10 min	10 min HIER, 10 min pepsin	DAKO stringency, 65 degrees celcius, 5 min
175	He2DNP chr 17 Dig	Ventana	Ultra	6 hours	20 minutes	3x8 minutes SSC, 72, 24 minutes
181	Inform Her2 Dual ISH DNA probe CKTL.	Ventana/Roch	Ventana Bench Mark XT	6 hours	52 minutes	SSC @ 72 deg. for 16 minutes
186	Pathvysion Her2	Abbott Molecular	Hybrite	16 hr	20min	Post Hybridization buffer73 C, 2.5 min
194	Pathvysion Her-2 DNA Probe Kit	Abbott	Thermobrite	24hrs	3min steam retrieval	(1) 2xSSC/0.3%NP-40 @roomtemp until coverslip falls off. (2) 2xSSC/0.3%NP-40 @72C for 2min. (3) airdry slides in dark. (4) counterstain slide.
197	Her2/Cep17	Vysis	Hybrite	18h	35min. 80C NaSCN, 11 min. 37C pepsin	2xSSC, 0.3%igepal, 72C, 2 min.
202	Abbott Her2 FISH probe	Inter Medico	Hybrite	16 hours at 37C	5 min at 73C	73oC 2X SSC/0.3%/NP40 for 2 minutes.
207	CHR17/HER2	Ventana	Benchmark Ultra	6.00Hrs	32MIN-CC1	silverwash1,2,3,-8min each.at 72 deg.
211	PathVysion HER-2	Abbott Molecular	ThermoBrite	20 hours	30 min	2X SSC/0.3% IGEPAL, 72C, 2 min