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Assessors' report for cIQc Run 62: ALK IHC (May 2016)

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Assessment performed in October 2016 at Toronto General Hospital, Ontario, Canada.

OVERVIEW

Run 62 consisted of a single-core tissue microarray containing 30 NSCLC cases with accompanying ALK FISH data. In total, 20 laboratories participated in Run 62. The assessors blindly reviewed all cores for all available slides returned to the cIQc office in time for the assessment meeting. For laboratories adhering to the kit staining protocol, cIQc assessment listed as "kt" are those that follow the strict readout rules established by Roche/Ventana. The testing material included 6 positive cases. Even one false-negative case results in <90% accuracy/concordance with reference laboratory and FISH results. Therefore, the overall result for any laboratory that produced even one false-negative result is designated as "suboptimal".

RESULTS

Participant-specific feedback for ALK IHC is summarized below:

Table with 3 columns: Lab ID, IHC Status*, and Comments. Rows include lab IDs 101, 102, 109, 109kt, 110, 111_1, 111_2, 112, 114, 115, 116, 116kt, 123, 125, 126, 146, 149, 176, 189kt, 194kt, 202, 217, and 220.

*Based on cIQc assessor consensus



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Garrattograms from self-assessment and after cIQc assessment of ALK IHC are provided in Supplementary Figure 1. Supplementary Table 1 summarizing staining protocols and Supplementary Table 2 summarizing descriptive statistics can also be found at the end of this document. Quality control methodologies of immunohistochemical assessment are evolving, and numeric results should be interpreted with this reservation. Your regular participation in cIQc is greatly appreciated and we look forward to continuing to work with you and the Canadian Association of Pathologists – Association Canadienne des Pathologistes.

Table S1. Reported ALK IHC staining protocols.

Lab ID	Ag Retrieval Method	Time for Ag Retrieval (min)	Ab Clone	Ab Dilution	Ab Supplier/Vendor	Ab Lot No.	Time for Ab Incubation (min)	Detection System	Amplification (Y/N)	Enhancement (Y/N)	Chromogen
101	HEAT (CC1)	64	5A4	1:25	NOVOCASTRA	6039071	16	OPTIVIEW	YES	COPPER	DAB
102	DAKO 3IN1 High pH	10/20/10	5A4	1:40	LEICA	6039189	60"	DAKO FLEX+	YES	CUSO4	DAB+
109	HIER HIGH pH (CC1)	40 MIN	D5F3	RTU	ROCHE/VENTANA	F01706	16 MIN	OPTIVIEW	Y	Y	DAB
110	DAKO PT High ph 9.0@97 C	20 min	5A4	1:50	Biocare	81715	30 min	DAKO ENVISION FLEX: Flex+30 Ms	Y- DAKO Mouse Linker	N	DAB
111_1	CC1	72min	5A4	1/25	Novacastra	6042962	60 min	Optiview	Yes	Copper	DAB
111_2	CC1	80min	5A4	1/25	Novacastra	6042962	60 min	Optiview	Yes	Copper	DAB
112	BOND EPITOPE RETRIEVAL 2 pH 9.0	30 minutes	5A4	1:100	Novocastra "Leica"	6028806	15 minutes	BOND Polymer Refine Detection	no	no	DAB
114	CC1	64	5A4	1/25	Biocare	21014	16	Optiview	Y	Copper	DAB
115	EnVision Flex TRS, High Ph	30 min	D5F3	1/100	cell signaling	5633	30 min	EnVision Flex	N	N	DAB
116	CC1	92 MIN	D5F3	RTU	VENTANA	F06019	16 MIN	OPTIVIEW DAB	Y	COPPER	DAB
125	Dako EnV FLEX TRS high pH	20 min	5A4	1/50	Novocastra/Leica	6028806	20 min	Dako EnV FLEX	Y	N	DAB
126	steam, EDTA, ph 8.0	45 minutes	D5F3	1:250	cell Signaling	5	30 minutes	mACH 4, HRP, Biocare	no	no	DAB, Betazoid
146	Flex TRS HIGH	20	5A4	1/100	Biocare	81715	25	EnVision FLEX	N	N	DAB
149	PT Link high pH	20 min at 97C	5A4	1:50	Novocastra	10107434	30	EnVision Flex	Yes	Yes	DAB
176	CC1	32	ALK01	Predilute	Ventana/Roche	F00267	32	OptiView	N	N	DAB
189	CC1	92	D5F3	pre-dilute	Ventana	unknown	16	OptiView	Y	N	DAB
194	HIER	92	D5F3	pre-dilute	ROCHE/VENTANA	F06019	16	OptiView DAB detection kit	Y	Y	DAB
202	Leica ER2 citrate Buffer 9.5	20 min	5A4	1/10	novocastra/leica	6039071	15 min	Refine Detection kit Leica	no	no	DAB
217	HIER CC1	72	D5F3	RTU	Roche	601026	36	Optiview	Y	Y	DAB
220	CC1	92	5A4	1:30	Leica	6042962	120	Opti-View	N	N	DAB

Table S2. Descriptive statistics for ALK IHC based on a) cIQc assessment and b) self-assessment.

cIQc Assessment

a)	cIQc Lab ID	Total n	% scorable	Pairwise complete observations	Concordance with FISH (%)	Cohen's kappa
	101	30	90	27	27/27 (100%)	1
	102	30	90	27	27/27 (100%)	1
	109	30	93.33	28	27/28 (96%)	0.89
	110	30	93.33	28	28/28 (100%)	1
	111_1	30	93.33	28	28/28 (100%)	1
	111_2	30	90	27	27/27 (100%)	1
	112	30	90	27	27/27 (100%)	1
	114	30	93.33	28	28/28 (100%)	1
	116	30	93.33	28	28/28 (100%)	1
	123	30	93.33	28	28/28 (100%)	1
	125	30	90	27	27/27 (100%)	1
	126	30	90	27	26/27 (96%)	0.9
	146	30	90	27	27/27 (100%)	1
	149	30	90	27	27/27 (100%)	1
	176	30	93.33	28	28/28 (100%)	1
	189	30	93.33	28	28/28 (100%)	1
	194	30	90	27	27/27 (100%)	1
	202	30	90	27	27/27 (100%)	1
	217	30	90	27	27/27 (100%)	1
	220	30	90	27	27/27 (100%)	1

Self-assessment

b)	cIQc Lab ID	Total n	% scorable	Pairwise complete observations	Concordance with FISH (%)	Cohen's kappa
	101	30	90	27	27/27 (100%)	1
	102	30	90	27	27/27 (100%)	1
	109	30	93.33	28	28/28 (100%)	1
	110	30	96.67	29	29/29 (100%)	1
	111_1	30	90	27	27/27 (100%)	1
	111_2	30	90	27	27/27 (100%)	1
	112	30	96.67	29	29/29 (100%)	1
	114	30	93.33	28	28/28 (100%)	1
	115	30	96.67	29	29/29 (100%)	1
	116	30	93.33	28	28/28 (100%)	1
	125	30	96.67	29	29/29 (100%)	1
	126	30	96.67	29	29/29 (100%)	1
	146	30	90	27	27/27 (100%)	1
	149	30	96.67	29	29/29 (100%)	1
	176	30	96.67	29	29/29 (100%)	1
	189	30	90	27	27/27 (100%)	1
	194	30	100	30	30/30 (100%)	1
	202	30	93.33	28	28/28 (100%)	1
	217	30	90	27	27/27 (100%)	1
	220	30	86.67	26	26/26 (100%)	1