Run 36 Assessment Meeting

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Participants: J Garratt, B Gilks, G Fischer, Lillian Lee, T Baskin, K Steven, B Heitoff, S Genske, S Puchalski, L Manning, M Umali, M Rosset, Farah Hague, S Ji, P Pahlavan, D Gomez, J Kline, H Qiu, C Santos, L Lucman, K MacDonald

We were able to hold this assessment meeting in Winnipeg as a result of receiving a grant from Canadian Partnership Against Cancer, which paid the travel expenses of the members of the review panel who travelled to the meeting. This funding from CPAC will also allow us to proceed to get full accreditation as an external proficiency testing program, and improve the quality of the service we provide, something that was not possible when we were an unfunded program.

This breast biomarker run assessed ER, PR and HER2 staining on a 60 core tissue microarray, with each core consisting of a unique case of invasive breast carcinoma.
FN = false negative
FP = false positive

HER2

Three cores were considered unsatisfactory by multiple labs and were therefore removed from further consideration (cores 9, 25 and 59). This left 57 evaluable cores, with 53 participating labs (57 x 53 = 3021 individual results entered).

Based on the self assessment results, there were six false negative results (self-reported as neg or 1+ result, for a case with HER2 amplification) and 5 false positive results (3+ immunostaining result for a case without amplification), i.e. 11/3021 potential results were incorrect. No lab had more than a single incorrect result. Thus, based on the self-assessment results, HER2 immunostaining continues to be excellent for participating laboratories.

All the false positive results were for core 42, a case that was scored as 2+ by a large majority of participating labs, but which did not show HER2 amplification by FISH. At the time of assessment meeting, all false positive results for which slides were available review were considered to be interpretive overcall of 2+ staining as 3+, resulting in a false positive result on self assessment, and thus staining was considered technically optimal for each of these labs. Similarly, all false negative results where slides were available at the assessment meeting were, based on

review, explainable as interpretive error (for example, as a result of no tumor cells being present in the sample). Thus results based on review, were even better than based on self-assessment results!

There were 46 slides available for review at the time of the assessment meeting. The slides from each participating laboratory were reviewed by the assessment team, with particular attention to the false negative and false positive results described above. For the labs with no false negative for false positive results, general staining quality was noted (tissue damage as a result of antigen retrieval, background staining, etc.). With HER2 staining, there is a range of staining intensities used by different labs, but this doesn't interfere with the ability to identify true positive or true negative cases, so subtle differences in staining intensity were not commented on. Results of this assessment are noted below.

101 – Optimal
102 – Intense staining with increased number of 2+ staining.
103 – False Positive core 42 - Over interpretation by lab. Called 2+ by other labs in the survey. Technically optimal staining
105 – Optimal
106 – Optimal
107 – Optimal
109 – Optimal
111 – Optimal
112 – Optimal
114 – Optimal
115 – Optimal
116 – False Positive core 42 - Over interpretation by the laboratory. Called 2+ by other labs in the survey. Technically optimal staining
117 – False Negative for Core 36 - No slide received for assessment
119 – Optimal
120 – False Negative for core 13. Sampling problem with no tumour present – marked unsatisfactory on assessment. Technically optimal staining
123 – Optimal
124 – No slide received
125 – Optimal
126 – FN33 Data entry error only –adjusted. Technically optimal staining
127 – Optimal
129 – Excellent assessment results but weak staining, overall
133 – Optimal
135 – Excellent assessment results but slightly weak staining
136 – FN58 No slide received for assessment
138 – Optimal

139 – No slide received
145 – Optimal
147 – FN13 On assessment review - no tumour present in Core 13. Technically optimal staining
149 – Optimal
150 – Optimal
151 – Optimal
152 – Optimal
153 – Optimal
155 – Optimal
157 – Optimal
160 – Weak staining with high number of 2+ cores. Less spread between 1+ 2+ 3+ staining.
161 – Optimal
162 – FP42 Core 42 considered to be 2+ by assessment team, i.e. an interpretative error. Technically optimal staining
164 – Optimal
167 – Excellent assessment results but overall weak staining
170 – Optimal
175 – Optimal
181 – FN9 Optimal staining – Sampling issue - Interpretative error and revised to unsatisfactory by assessment team. Technically optimal results
186 – Intense staining with a resulting increased number of 2+staining
187 – Optimal
188 – Excellent assessment results but overall weak staining
189 – FP42 - Core 42 considered to be 2+ by assessment team, i.e. an interpretative error. Technically optimal staining
190 – High number of 2+ cases. Possibly caused by high Ab concentration
191 – Optimal
194 – Optimal
198 – Optimal
199 – No slide received for assessment
202 - FP42 - No slide received for assessment

ER

With ER staining, most cases are clearly positive or negative, and identified as such by all labs. These cases are relatively uninformative about how a lab performs, as it is the cases with weaker staining that are the ones that result in false negative test results. With ER testing to date, false positive results have been much less of a problem than false negative results, but we (CIQC) and UKNEQAS have both started seeing false positive results with the newest generation of highly sensitive detection systems. In particular, an issue has been identified with the use of the 6F11 Ab and the Leica Bond combination.

Based on the self-assessment results, five cores were identified as being of particular interest for this run: cores 2, 14, 23, 36 and 42. These cores were noted to be neg, neg, pos, neg, pos by the reference lab, respectively, but for each core there were significant numbers of labs with both positive and negative staining results. (All these cores were PR neg according to the reference lab; as ER neg/PR pos is rarely encountered, it is worth checking PR status in cases where ER staining is equivocal, as if PR pos it suggests that the tumor is also ER pos). It remains a challenge in equivocal cases to know if they are truly ER positive, in a clinically meaningful way (i.e. will that tumor respond to tamoxifen). As these cores clearly posed the greatest challenge for participants they were reviewed for each of the participating labs, with particular attention to any technical factors that might account for the variable staining results. On review of these cores, core 42 showed variable staining, in a pattern that we attribute to variable fixation, which would account for the inconsistent results reported. Cores 2, 23, and 36 showed very weak focal staining, and based on a small sample size in a TMA core it would be possible to miss the staining, even with well-optimized staining. We therefore excluded these cores from analysis. Core 14 was, based on the review, considered a true negative result, but some equivocal nuclear blush was seen on some slides – this is of uncertain significance, and we chose to exclude this core from further analysis as being non-informative. As well as these five cores, other cores where false negative or false positive results were recorded by self-assessment (noted below) were also carefully reviewed. 73 labs entered self assessment results for ER, and slides were available for review from 64 labs at the time of the assessment meeting. The reference values for this array were based on the consensus of staining results from reference laboratories, as described previously (Makretsov N et al., Arch Pathol Lab Med 2011 Jul;135(7):874-81).

Cores 13, 25 and 59 were excluded from further consideration based on the large number of unsatisfactory results entered at the time of self assessment, leaving 57 cores as the basis of this assessment run. Results of assessment are indicated below. Note that labs tended to show either “false positive” or “false negative” results, but not both. Although many of the false positive results were, on review, considered to

not be true positive staining of tumor cells (staining of lymphocytes, stromal cells or normal breast epithelial cells were among the reasons for false positive results recorded at self-assessment), a few false positive results remain. This does represent a change from past runs, where lack of sensitivity was the only significant issue identified, relative to the reference values. We now have a few labs where there are cases that stain positively for ER (albeit weakly) that are not identified as positive by the reference lab. This raises the question of what the correct result is in these cases. Based on the observation that our data on correlation between ER positivity and tamoxifen response is based on the results obtained using the staining protocols used in the reference labs, we are considering these to be false positive results (or at least of unproven ER positive status). There is a correlation between seeing these false positive results and use of the Leica Bond-Max system with 6F11 antibody, as noted previously. We also saw false positive staining with the same platform and SP1 Ab used at a high concentration (1:50) dilution. We would therefore suggest that labs using this system carefully evaluate their protocol.

We are currently involved in a study of weakly positive ER cases to try to learn more about these problematic cases, and shed some light on their clinical significance.

101 – Optimal
102 – Optimal
103 – Optimal – slightly light staining
105 – Many unsatisfactory results due to cores falling off. Antigen retrieval appears to be too harsh.
106 – FP27,28,29 No slides received for review
107 – Optimal
109 – Optimal
111 – FP28 but results technically optimal. Core 28 not considered positive by assessment panel
112 – Optimal
113 - FN35 no slide received for interpretation
114 – FP28 Core 28 negative by assessment panel. Technically optimal
115 – Optimal
116 – Optimal
117 – FN38 No slides received for review
119 – Optimal
120 – FN38, FP49 Core 38 No tumour present. Sampling issue. Core 49 - benign components called positive. Core interpreted to be negative by the panel, so technically optimal staining.
122 – FP5,15,28,29 Cores 5, 15, 28, 29 confirmed as false positive by the panel. It is recommended that the laboratory consider switching to the SP1 clone. Sub-optimal staining

123 – Optimal
124 – FN1,40 No slide return to cIQc for evaluation.
125 – FP28 Interpretative error, stromal cells have been called positive by the lab. Technically optimal
126 – Optimal
127 – Optimal
128 - Optimal
129 – FP27,28 Confirmed by panel to be false positive
132 – FP 5,21,27,28,29,48. Many false positives No slide to review
133 – FP 26,28 Core 26 showed stromal cell staining, and core 28 was considered equivocal on review
134 - Optimal
135 – Good self-assesment results but with lesser quality, weaker staining, than seen in other labs
136 – FN40 no slides returned to cIQc
138 – Optimal
139 – No slide received
141 – Optimal
143 – Optimal
144 - Optimal
145 – FP28 Optimal technical staining. Assessment team did not support positive call by lab of core 28.
146 – FP49 Optimal technical staining. Assessment team did not support positive call by lab of core 49. Data entry error?
147 –FN7 Optimal technical staining. Core sampling error as no tumour cells present in core 7
148 - Optimal
149 –Optimal slight weak staining
150 – Optimal
151 – FP28 Core 28 confirmed to be a false positive by assessment team. Overall technical quality is good.
152 – Optimal
153 – Optimal
155 – Optimal
157 – Optimal
159 - No self assessment results submitted. Staining considered slightly weak by assessment team.
160 – Optimal.
161 – Optimal
162 – FP28,48 Intense general staining with many stromal cells and lymphocytes staining. 28 not considered positive and core 48 considered equivocal by the assessment team
163 - Optimal

164 – Optimal
165 - Optimal
167 – Optimal
168 - FN1 Core 1 was considered to be a true false negative by the assessment team. Possible technical issue with antibody distribution, as it is at the corner of the array, near the slide label.
170 – Optimal
173 – FN3,18,30,31,32,44,50 many unsatisfactory results reported on self assessment. No slides returned to cIQc for evaluation. It is advised that the lab follows up on the assessment.
175 – Optimal
177 – Optimal
180 - Optimal
183 – Optimal
184 - Optimal
186 – FN1 Core 1 confirmed to be a weak positive on review. Overall staining is light but adequate.
187 – Optimal
188 – FN1,60 general blush Core 1 considered weak positive by the assessment team. Core 60 considered unsatisfactory on assessment – no tumour present. Sampling issue
189 – FP9,26,28 Core 49 unsatisfactory (benign stromal cells called positive), core 26 negative on review, core 28 is considered a weak positive by the assessment team
190 – Optimal
191 – Optimal
192 – Optimal
194 – FP49 --Core 49 considered negative by the assessment team. Benign elements staining and called positive by the laboratory. Optimal staining
196 – FN1,7,40 No slides received for assessment.
198 – Optimal
199 – No slides received for assessment.
202 - FN1, FP29 no slides received for assessment
208 –FP9 Core 9 was considered unsatisfactory by the assessment team. Benign stromal cells only staining
209 – FN40 General staining is very weak. Core 40 was considered to be a weak positive by the assessment team.

PR

PR immunostaining continues to show more variability among participating laboratories than HER2 or ER. This is unlikely to change unless new primary antibodies appear on the market that give more consistent staining results. To the best of our knowledge, there is no solution for the variable staining for PR evident on a quick look at the Garratogram. In fact, a look at the results from labs using pre-dilute Abs (ready to use) show that they are not doing any better than those labs using concentrate, so there is no quick fix available for the variable PR staining we see, from lab to lab. Determination of what the correct result should be, in those cases where there is considerable interlaboratory variation in PR results for a given case (mentioned above with respect to ER staining) is even more problematic for PR, where validation against response to tamoxifen in a historical case series, as has been done by one of our reference labs for ER, is not possible. **Because of these very consistent and currently insoluble problems in PR staining, the quality of staining was assessed more subjectively for PR than for HER2 or ER**, and most labs were able to achieve satisfactory results. cIQc will be looking more closely at the variability issue in PR testing and hope to report back to the group by the end of the year.

As for ER, there were cores that showed considerable variability in PR staining, namely cores 2, 10, 16, 19, 40 and 47. All these cases were consistently ER positive, except for core 2, which showed variable ER staining, from lab to lab. These cores were neg, neg, pos, neg and neg, respectively, in PR staining done at the reference lab. Cores 13, 20, 25, 59 and 60 were eliminated from further consideration as there were too many unsatisfactory results.

71 labs entered self assessment results for PR immunostaining, and slides were available for review at the assessment meeting from 61 labs.

101 – Satisfactory
102 – Satisfactory
103 – Satisfactory Good overall stain with picking up additional PR positive cases, compared to reference (e.g. staining
105 – Satisfactory
106 – No slide
107 – Satisfactory
109 – Satisfactory
111 – Satisfactory Core 16 was considered neg by assessment team and for Core 17 only benign cells were staining, based on review
112 – Satisfactory
114 – Satisfactory
115 – Satisfactory

116 – Satisfactory
117 – No slide
119 – Satisfactory
120 – Satisfactory
122 - Satisfactory
123 – Satisfactory
124 – No slide
125 – Satisfactory
126 – Satisfactory
127 – Satisfactory Cores 29 and 30 considered negative on review
128 – Satisfactory Core 16 confirmed as positive on review, Core29 showed a faint blush (weak positive) while core 30 was considered equivocal on review
129 – Satisfactory
132 - No slide
133 – Satisfactory
134 - Satisfactory
135 – Satisfactory
136 – Satisfactory
138 – No slide
139 – No slide
141 – Very weak nuclear positivity seen in cases that were not positive in other labs (e.g. cores 15, 29, 30)
143 – Satisfactory
145 – Satisfactory
146 - Satisfactory
147 – Satisfactory
149 – Satisfactory
150 – Satisfactory
151 – Satisfactory
152 – Satisfactory
153 – On review, there was weak nuclear positivity seen in cases that were not positive in other labs (e.g. cores 15, 29, 30)
155 – Satisfactory
157 – Satisfactory
160 – Satisfactory
161 – Satisfactory
162 – Satisfactory
163 – On review, there was weak nuclear positivity seen in cases that were not positive in other labs (e.g. cores 28, 29, 30,40)
164 – Satisfactory
165 - Intense staining, including weak nuclear positivity seen in cases that were not positive in other labs (e.g. cores 28, 29, 30,40)
167 – Satisfactory

168 - Satisfactory
170 – Satisfactory
173 – No slide
175 – Satisfactory Core 29 very weak pos, core 40 considered negative on review
177 – Satisfactory
183 – Satisfactory Core 15 considered negative, cores 29 and 30 equivocal on review. Core 40 weak positive
184 - Satisfactory
186 – Satisfactory
187 – Satisfactory
188 – Satisfactory
189 – Satisfactory
190 – Satisfactory
191 – Satisfactory
192 – Cores 2, 10, 16, 29, 30 and 40 positive on review, i.e. positivity seen in cases that were not positive in other labs
194 Satisfactory
196 – No slide
198 – Satisfactory, but overall staining weaker than in other labs
199 – No slide
202 - No slide
208 – Satisfactory
209 – Satisfactory

HER2

Labs/Cores	101	102	103	105	106	107	109	111	112	114	115	116	117	119	120	123	124	125	126	127	129	133	135	136	138	139	145	147	149	150	151	152	153	155	157	160	161	162	164	167	170	175	181	186	187	188	189	190	191	194	198	199	202	R1
1	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	2	3	3	3	3	2	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	2	3	3	3	3	3	3	3	3
2	N	2	1	N	N	N	N	N	N	N	U	1	N	1	N	N	1	U	N	N	N	N	N	N	1	N	N	2	N	N	1	N	N	N	N	2	N	N	1	N	1	N	N	1	N	U	1	N	N	N	1	N	1	N
3	N	1	N	N	U	N	N	N	N	N	N	1	N	1	N	N	N	N	U	N	N	1	N	1	1	N	N	1	N	N	1	1	N	N	1	2	N	N	1	1	1	N	1	1	U	N	1	N	U	N	N	N	N	N
4	N	2	2	2	1	N	1	2	1	2	2	2	2	2	N	2	2	2	1	1	1	2	2	1	2	1	1	2	N	1	2	2	2	1	2	2	1	2	2	1	1	1	2	1	2	N	2	N	2	1	2	N	2	2
5	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	2	3	3	3	3	3	3	3	3	3
6	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	2	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
7	N	N	N	N	N	N	N	N	N	N	U	N	N	N	N	U	1	U	U	N	N	1	U	U	U	U	N	N	N	U	N	N	N	N	1	1	N	U	N	N	N	N	N	N	N	1	N	U	U	N	N	N	N
8	N	2	2	1	N	N	1	2	N	N	2	1	1	2	2	2	2	2	1	1	1	1	1	1	2	1	N	2	N	1	2	2	1	1	1	2	1	2	2	1	1	2	2	2	1	N	N	2	N	U	1	2	N	2	N
9	3	U	U	3	2	U	3	3	2	3	U	U	U	U	U	U	U	U	2	U	U	3	2	U	U	U	3	U	U	U	U	3	3	2	3	U	U	U	U	2	2	3	N	U	3	U	U	3	3	U	U	3	U	3
10	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	2	3	3	3	3	2	3	3	3	3	3	3	3	3	3	3	3	2	3	3	3	3	3	3	3	3	3	2	3	3	3	3	3	3	3	3
11	N	1	2	1	1	N	1	1	N	1	U	1	1	2	U	U	1	U	1	1	1	U	U	U	U	U	1	U	U	U	1	1	1	1	1	2	1	U	1	U	1	U	U	U	2	N	U	U	2	U	2	N	2	1
12	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	2	3	3	3	3	3	3	3	3	2	3	3	3	3	3	3	3	3	3
13	3	U	U	3	U	U	3	3	3	3	U	U	U	U	N	U	U	U	3	U	U	3	3	U	U	U	3	N	U	U	U	3	3	3	3	U	U	U	U	3	3	3	N	U	3	U	U	3	U	U	U	3	U	3
14	N	2	N	N	N	N	N	N	N	N	N	N	N	1	N	N	N	N	N	N	N	N	N	N	N	N	N	2	N	N	2	N	N	N	2	N	N	1	N	1	N	1	N	N	1	N	N	N	N	1	N	N	N
15	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
16	N	2	2	1	1	1	1	2	1	2	U	2	1	2	1	2	2	2	1	1	1	2	2	1	2	1	1	2	N	1	2	1	1	1	2	2	1	2	2	1	2	2	2	2	2	2	N	2	2	2	2	2	N	2	2
17	N	1	2	1	N	N	1	2	N	N	U	1	1	2	N	N	1	1	1	N	N	1	N	N	U	U	1	2	N	1	1	1	N	1	1	2	N	N	1	1	1	1	1	1	N	N	1	N	1	1	1	U	1	N
18	N	2	2	U	U	1	U	2	U	2	2	2	2	2	1	2	2	2	U	1	1	U	1	1	2	1	1	1	N	1	2	2	1	2	U	2	1	2	2	1	1	1	2	2	U	N	2	1	U	1	2	N	2	2
19	N	1	1	1	N	N	N	N	N	N	U	1	1	1	N	1	1	1	1	N	N	1	N	N	1	U	1	1	N	N	1	1	N	1	1	2	N	1	1	U	1	N	1	1	1	N	N	2	N	2	N	1	N	2	N
20	U	U	U	1	U	U	N	U	N	N	U	N	1	N	N	N	U	U	U	U	N	U	U	N	U	U	N	1	U	U	1	N	U	N	N	U	U	N	U	U	U	N	N	U	U	N	N	N	U	N	U	N	N	N
21	N	2	2	2	1	N	1	2	1	N	2	2	1	2	1	2	2	2	1	1	1	2	1	1	2	1	1	2	N	1	2	2	1	1	2	2	1	2	2	1	2	1	2	2	2	N	2	N	2	1	2	N	2	N
22	N	U	U	1	N	U	N	N	N	N	U	U	N	1	U	U	U	U	N	U	N	1	N	U	U	U	N	U	U	U	1	N	N	N	N	2	U	U	U	N	1	N	U	U	N	U	U	N	N	U	U	N	N
23	N	N	N	N	N	N	N	N	N	N	N	N	N	1	N	N	N	U	N	N	N	N	N	N	N	N	N	N	N	N	1	N	N	1	N	N	N	1	N	1	N	N	N	N	N	N	N	N	N	N	N	N	N
24	1	2	1	1	1	N	1	1	1	2	1	2	1	1	N	1	N	1	1	N	N	1	N	N	1	N	2	1	N	1	1	1	1	N	1	1	1	1	1	1	1	1	1	1	1	N	2	2	2	N	N	N	1	2
25	U	U	U	U	U	U	U	U	U	U	2	U	N	U	2	U	U	U	U	U	U	U	U	2	N	U	N	U	U	U	U	U	U	U	U	U	U	U	U	U	U	1	1	U	U	N	U	U	U	U	U	U	U
26	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	1	N	N	N	N	N	N	N	N	N	N	N	N	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
27	U	N	N	N	N	N	N	N	N	N	N	1	N	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	1	N	N	N	N	N	1	N	N	1	N	N	1	N	N	1	N	N	N	N	N	N	N	N
28	1	2	2	1	2	1	1	2	1	2	2	2	2	1	2	1	1	1	2	2	1	1	2	2	1	2	N	1	1	N	1	1	1	2	1	1	2	1	2	1	1	2	2	2	1	1	1	2	2	2	1	2	N	2	2
29	N	N	N	1	N	N	N	N	N	N	N	N	N	1	N	N	N	N	N	N	N	1	N	N	N	N	N	N	N	N	1	N	N	N	1	N	N	1	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
30	N	2	2	2	1	1	1	2	1	N	2	2	2	2	2	2	2	2	1	1	1	2	1	1	2	1	1	2	N	1	2	2	1	2	2	2	1	2	2	2	2	2	2	2	2	N	2	1	2	2	2	N	2	N
31	N	2	1	1	N	N	N	N	N	N	1	1	N	1	N	N	1	1	1	N	N	1	N	N	1	2	N	1	1	N	N	1	N	1	2	N	1	1	N	N	1	1	N	N	1	1	N	N	1	1	N	N	1	N
32	N	U	U	1	1	N	1	N	N	1	U	U	N	1	U	U	U	U	1	U	U	1	2	U	U	U	1	U	U	U	1	1	N	1	1	U	U	U	U	1	1	N	U	U	N	N	U	1	2	U	U	N	U	1
33	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	N	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3	3
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35	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	1	N	N	N	1	N	N	N	1	N	N	1	N	N	1	N	N	N	N	N	N	N	N
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3	3+
2	2+
1	1+
N	Negative
U	Unsatisfactory


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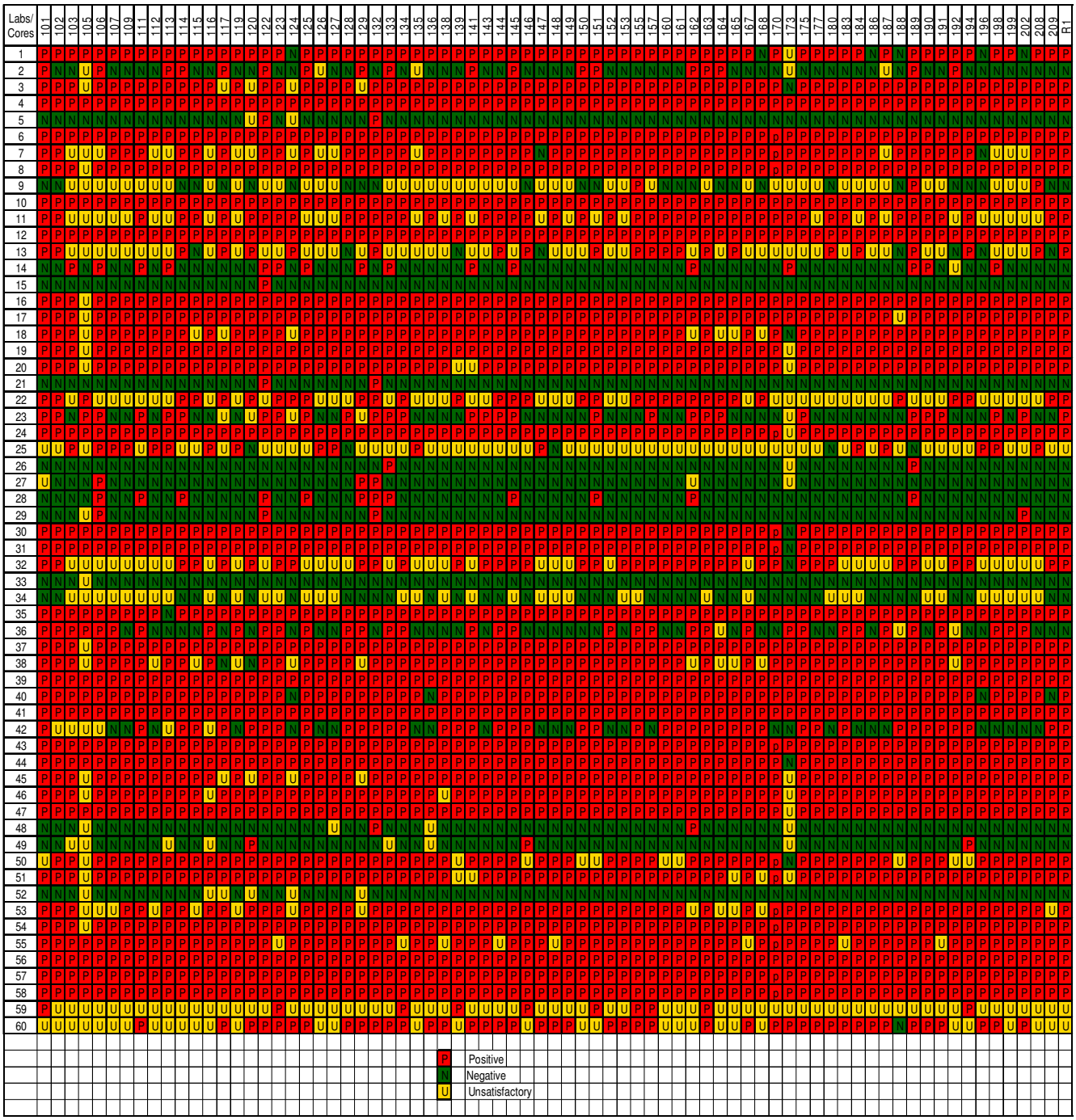
ER


Positive
Negative
Unsatisfactory


cIQc
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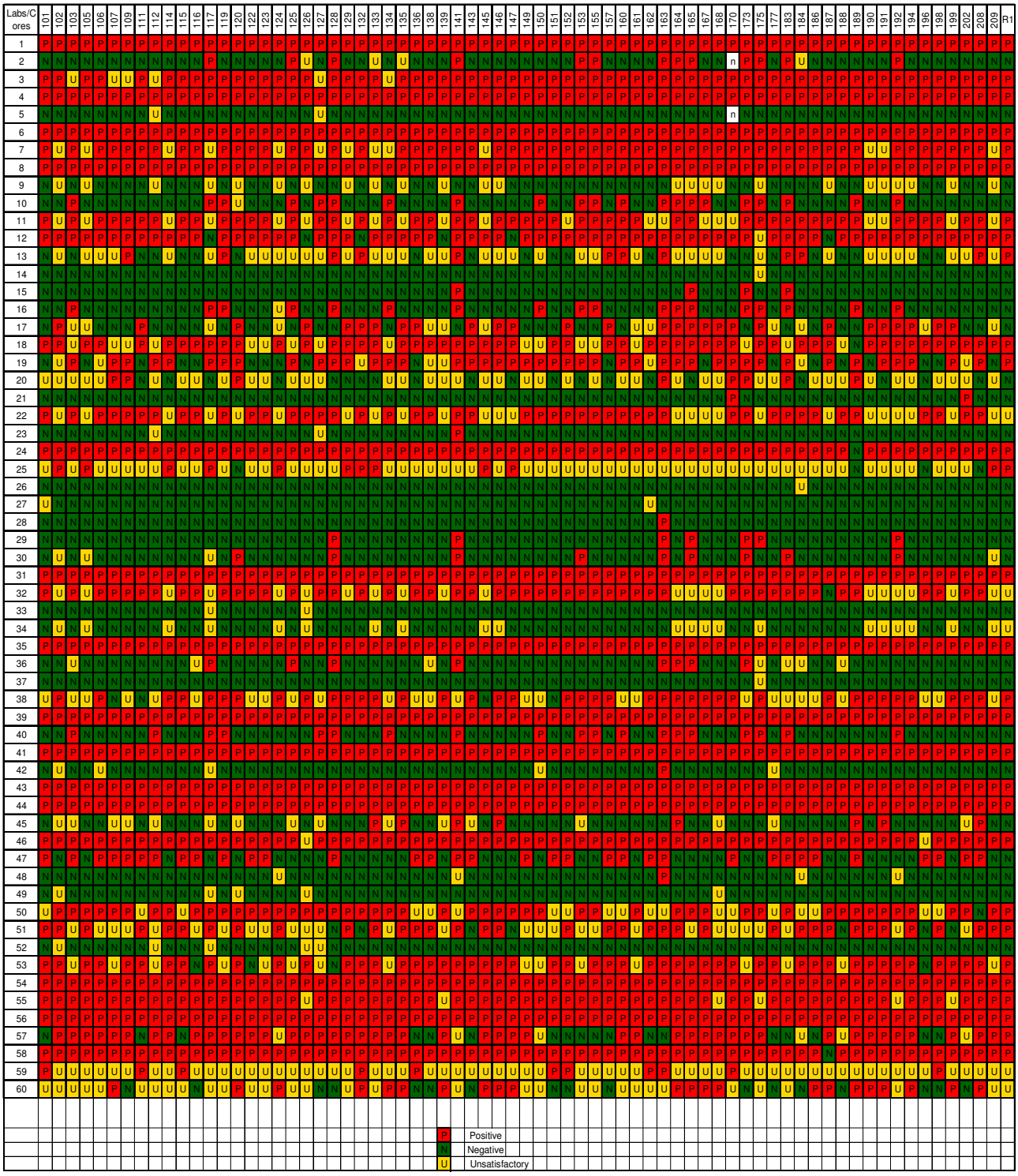
PR


Labs/Cores
P Positive
N Negative
U Unsatisfactory

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Descriptive Statistics HER2

Test lab name	total n	% scorable	pairwise complete observations	concordance with reference (%)	sensitivity	specificity	PPV (positive predictive value)	NPV (negative predictive value)	Cohen's kappa
101	60	88.33	53	53/53 (100%)	1	1	1	1	1
102	60	85	49	49/49 (100%)	1	1	1	1	1
103	60	83.33	49	48/49 (98%)	1	0.97	0.92	1	0.95
105	60	90	53	53/53 (100%)	1	1	1	1	1
106	60	81.67	48	48/48 (100%)	1	1	1	1	1
107	60	88.33	51	51/51 (100%)	1	1	1	1	1
109	60	91.67	53	53/53 (100%)	1	1	1	1	1
111	60	93.33	55	55/55 (100%)	1	1	1	1	1
112	60	90	53	53/53 (100%)	1	1	1	1	1
114	60	93.33	56	56/56 (100%)	1	1	1	1	1
115	60	70	41	41/41 (100%)	1	1	1	1	1
116	60	90	52	51/52 (98%)	1	0.98	0.92	1	0.95
117	60	90	51	50/51 (98%)	0.92	1	1	0.98	0.94
119	60	90	52	52/52 (100%)	1	1	1	1	1
120	60	88.33	51	50/51 (98%)	0.92	1	1	0.97	0.95
123	60	85	49	49/49 (100%)	1	1	1	1	1
124	60	85	49	49/49 (100%)	1	1	1	1	1
125	60	76.67	45	45/45 (100%)	1	1	1	1	1
126	60	76.67	44	44/44 (100%)	1	1	1	1	1
127	60	83.33	48	47/48 (98%)	0.92	1	1	0.97	0.94
129	60	88.33	51	51/51 (100%)	1	1	1	1	1
133	60	86.67	51	51/51 (100%)	1	1	1	1	1
135	60	88.33	53	53/53 (100%)	1	1	1	1	1
136	60	86.67	49	48/49 (98%)	0.92	1	1	0.97	0.94
138	60	78.33	45	45/45 (100%)	1	1	1	1	1
139	60	71.67	42	42/42 (100%)	1	1	1	1	1
145	60	93.33	55	55/55 (100%)	1	1	1	1	1
147	60	90	51	50/51 (98%)	0.92	1	1	0.97	0.95
149	60	78.33	46	46/46 (100%)	1	1	1	1	1
150	60	80	47	47/47 (100%)	1	1	1	1	1
151	60	90	53	53/53 (100%)	1	1	1	1	1
152	60	95	55	55/55 (100%)	1	1	1	1	1
153	60	90	54	54/54 (100%)	1	1	1	1	1
155	60	91.67	55	55/55 (100%)	1	1	1	1	1
157	60	95	55	55/55 (100%)	1	1	1	1	1
160	60	83.33	49	49/49 (100%)	1	1	1	1	1
161	60	80	47	47/47 (100%)	1	1	1	1	1
162	60	85	49	48/49 (98%)	1	0.97	0.92	1	0.95
164	60	83.33	48	48/48 (100%)	1	1	1	1	1
167	60	88.33	52	52/52 (100%)	1	1	1	1	1
170	60	88.33	53	53/53 (100%)	1	1	1	1	1
175	60	93.33	55	55/55 (100%)	1	1	1	1	1
181	60	91.67	52	50/52 (96%)	0.86	1	1	0.95	0.9
186	60	86.67	49	49/49 (100%)	1	1	1	1	1
187	60	86.67	51	51/51 (100%)	1	1	1	1	1
188	60	86.67	51	51/51 (100%)	1	1	1	1	1
189	60	90	51	50/51 (98%)	1	0.97	0.92	1	0.95
190	60	91.67	54	54/54 (100%)	1	1	1	1	1
191	60	75	45	45/45 (100%)	1	1	1	1	1
194	60	83.33	48	48/48 (100%)	1	1	1	1	1
198	60	88.33	51	51/51 (100%)	1	1	1	1	1
199	60	90	54	54/54 (100%)	1	1	1	1	1
202	60	83.33	49	48/49 (98%)	1	0.97	0.92	1	0.95

Descriptive Statistics ER

Test lab name	total n	% scorable	pairwise complete observations	concordance with reference (%)	sensitivity	specificity	PPV (positive predictive value)	NPV (negative predictive value)	Cohen's kappa
101	60	93.33	55	53/55 (96%)	1	0.87	0.95	1	0.9
102	60	93.33	56	55/56 (98%)	1	0.94	0.98	1	0.96
103	60	81.67	48	45/48 (94%)	0.97	0.85	0.94	0.92	0.84
105	60	48.33	29	28/29 (97%)	1	0.88	0.95	1	0.91
106	60	81.67	48	42/48 (88%)	1	0.57	0.85	1	0.65
107	60	85	50	47/50 (94%)	0.94	0.93	0.97	0.87	0.85
109	60	86.67	51	49/51 (96%)	0.95	1	1	0.88	0.91
111	60	88.33	52	49/52 (94%)	1	0.79	0.93	1	0.84
112	60	81.67	48	46/48 (96%)	0.94	1	1	0.88	0.9
113	60	81.67	48	45/48 (94%)	0.97	0.85	0.94	0.92	0.84
114	60	95	57	55/57 (96%)	1	0.88	0.95	1	0.91
115	60	90	54	52/54 (96%)	0.95	1	1	0.89	0.91
116	60	78.33	46	44/46 (96%)	0.97	0.92	0.97	0.92	0.89
117	60	88.33	52	50/52 (96%)	0.97	0.93	0.97	0.93	0.91
119	60	81.67	48	45/48 (94%)	0.94	0.93	0.97	0.87	0.85
120	60	88.33	51	49/51 (96%)	0.97	0.93	0.97	0.93	0.9
122	60	88.33	52	44/52 (85%)	1	0.43	0.83	1	0.52
123	60	91.67	53	51/53 (96%)	1	0.86	0.95	1	0.9
124	60	81.67	48	45/48 (94%)	0.91	1	1	0.82	0.86
125	60	88.33	52	48/52 (92%)	1	0.71	0.9	1	0.79
126	60	83.33	49	47/49 (96%)	0.94	1	1	0.87	0.9
127	60	83.33	49	47/49 (96%)	0.94	1	1	0.87	0.9
128	60	95	55	53/55 (96%)	0.97	0.94	0.97	0.94	0.91
129	60	85	50	45/50 (90%)	1	0.67	0.88	1	0.74
132	60	96.67	57	51/57 (89%)	1	0.63	0.87	1	0.71
133	60	88.33	52	47/52 (90%)	1	0.64	0.88	1	0.72
134	60	91.67	53	52/53 (98%)	1	0.93	0.98	1	0.95
135	60	83.33	49	47/49 (96%)	0.94	1	1	0.87	0.9
136	60	86.67	51	48/51 (94%)	0.92	1	1	0.81	0.86
138	60	83.33	49	48/49 (98%)	0.97	1	1	0.93	0.95
139	60	90	53	51/53 (96%)	0.95	1	1	0.88	0.91
141	60	83.33	49	46/49 (94%)	1	0.79	0.92	1	0.84
143	60	91.67	54	53/54 (98%)	0.97	1	1	0.94	0.95
144	60	93.33	55	54/55 (98%)	1	0.93	0.98	1	0.95
145	60	91.67	54	50/54 (93%)	1	0.71	0.91	1	0.79
146	60	95	56	54/56 (96%)	0.98	0.94	0.98	0.94	0.91
147	60	90	52	48/52 (92%)	0.89	1	1	0.78	0.82
148	60	88.33	51	49/51 (96%)	0.95	1	1	0.88	0.91
149	60	86.67	51	49/51 (96%)	0.95	1	1	0.88	0.91
150	60	91.67	55	53/55 (96%)	0.97	0.94	0.97	0.94	0.91
151	60	93.33	55	53/55 (96%)	1	0.88	0.95	1	0.91
152	60	90	53	50/53 (94%)	0.95	0.93	0.97	0.88	0.86
153	60	88.33	52	50/52 (96%)	0.95	1	1	0.88	0.91
155	60	96.67	56	53/56 (95%)	0.98	0.87	0.95	0.93	0.86
157	60	96.67	56	54/56 (96%)	0.98	0.93	0.98	0.93	0.91
160	60	93.33	56	55/56 (98%)	0.98	1	1	0.94	0.96
161	60	93.33	56	55/56 (98%)	0.98	1	1	0.94	0.96
162	60	86.67	52	47/52 (90%)	1	0.67	0.88	1	0.74
163	60	95	55	53/55 (96%)	1	0.86	0.95	1	0.9
164	60	86.67	52	51/52 (98%)	1	0.93	0.97	1	0.95
165	60	88.33	53	52/53 (98%)	0.97	1	1	0.94	0.96
167	60	86.67	51	49/51 (96%)	0.97	0.93	0.97	0.93	0.9
168	60	86.67	52	50/52 (96%)	0.94	1	1	0.89	0.91
170	60	91.67	54	52/54 (96%)	0.95	1	1	0.88	0.91
173	60	68.33	40	30/40 (75%)	0.73	0.8	0.92	0.5	0.44
175	60	91.67	54	53/54 (98%)	1	0.93	0.98	1	0.95
177	60	90	53	52/53 (98%)	0.97	1	1	0.94	0.95
180	60	95	55	53/55 (96%)	0.95	1	1	0.88	0.91
183	60	86.67	51	49/51 (96%)	0.97	0.93	0.97	0.93	0.9
184	60	90	52	49/52 (94%)	0.95	0.93	0.97	0.87	0.86
186	60	90	53	50/53 (94%)	0.92	1	1	0.83	0.87
187	60	86.67	50	47/50 (94%)	0.94	0.93	0.97	0.87	0.85
188	60	91.67	54	51/54 (94%)	0.92	1	1	0.83	0.87
189	60	96.67	56	50/56 (89%)	1	0.63	0.87	1	0.7
190	60	88.33	52	51/52 (98%)	1	0.93	0.97	1	0.95
191	60	86.67	51	50/51 (98%)	1	0.93	0.97	1	0.95
192	60	86.67	52	49/52 (94%)	0.95	0.93	0.97	0.87	0.86
194	60	95	56	54/56 (96%)	0.98	0.94	0.98	0.94	0.91
196	60	91.67	53	47/53 (89%)	0.84	1	1	0.71	0.75
198	60	86.67	50	47/50 (94%)	0.97	0.86	0.95	0.92	0.85
199	60	83.33	50	47/50 (94%)	0.94	0.93	0.97	0.87	0.85
202	60	85	50	46/50 (92%)	0.94	0.86	0.94	0.86	0.8
208	60	90	53	50/53 (94%)	0.95	0.93	0.97	0.88	0.86
209	60	93.33	56	53/56 (95%)	0.93	1	1	0.84	0.88

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Descriptive Statistics PR

Test lab name	total n	% scorable	pairwise complete observations	concordance with reference (%)	sensitivity	specificity	PPV (positive predictive value)	NPV (negative predictive value)	Cohen's kappa
101	60	90	50	46/50 (92%)	0.88	0.96	0.96	0.88	0.84
102	60	73.33	44	43/44 (98%)	1	0.95	0.96	1	0.95
103	60	80	45	40/45 (89%)	0.96	0.82	0.85	0.95	0.78
105	60	78.33	47	46/47 (98%)	0.96	1	1	0.96	0.96
106	60	86.67	49	48/49 (98%)	1	0.96	0.96	1	0.96
107	60	86.67	48	45/48 (94%)	0.96	0.92	0.92	0.96	0.88
109	60	88.33	49	47/49 (96%)	1	0.92	0.92	1	0.92
111	60	95	53	47/53 (89%)	0.85	0.92	0.92	0.86	0.77
112	60	76.67	43	40/43 (93%)	0.96	0.9	0.92	0.95	0.86
114	60	86.67	52	52/52 (100%)	1	1	1	1	1
115	60	93.33	52	48/52 (92%)	0.89	0.96	0.96	0.89	0.85
116	60	90	50	46/50 (92%)	0.88	0.96	0.96	0.88	0.84
117	60	73.33	44	38/44 (86%)	0.96	0.72	0.83	0.93	0.71
119	60	90	51	47/51 (92%)	1	0.84	0.87	1	0.84
120	60	90	51	46/51 (90%)	0.93	0.86	0.9	0.9	0.8
122	60	86.67	49	46/49 (94%)	0.92	0.96	0.96	0.92	0.88
123	60	85	48	46/48 (96%)	0.96	0.96	0.96	0.96	0.92
124	60	80	47	46/47 (98%)	0.96	1	1	0.96	0.96
125	60	83.33	47	43/47 (91%)	1	0.83	0.85	1	0.83
126	60	73.33	43	40/43 (93%)	0.91	0.95	0.95	0.9	0.86
127	60	76.67	42	40/42 (95%)	1	0.9	0.91	1	0.9
128	60	96.67	54	44/54 (81%)	0.93	0.69	0.76	0.9	0.63
129	60	86.67	51	50/51 (98%)	1	0.96	0.96	1	0.96
132	60	98.33	54	51/54 (94%)	0.93	0.96	0.96	0.93	0.89
133	60	83.33	50	48/50 (96%)	1	0.92	0.93	1	0.92
134	60	81.67	45	42/45 (93%)	1	0.88	0.88	1	0.87
135	60	83.33	49	47/49 (96%)	1	0.91	0.93	1	0.92
136	60	95	52	47/52 (90%)	0.88	0.92	0.92	0.89	0.81
138	60	85	47	45/47 (96%)	0.96	0.96	0.96	0.96	0.91
139	60	78.33	45	44/45 (98%)	0.96	1	1	0.96	0.96
141	60	86.67	49	38/49 (78%)	1	0.54	0.69	1	0.55
143	60	95	53	48/53 (91%)	0.89	0.92	0.93	0.88	0.81
145	60	83.33	49	48/49 (98%)	0.96	1	1	0.96	0.96
146	60	88.33	51	49/51 (96%)	1	0.92	0.93	1	0.92
147	60	95	54	51/54 (94%)	0.93	0.96	0.96	0.93	0.89
149	60	86.67	49	47/49 (96%)	0.96	0.96	0.96	0.96	0.92
150	60	81.67	46	43/46 (93%)	1	0.88	0.88	1	0.87
151	60	95	52	48/52 (92%)	0.88	0.96	0.96	0.89	0.85
152	60	93.33	51	47/51 (92%)	0.92	0.92	0.92	0.92	0.84
153	60	86.67	49	43/49 (88%)	0.96	0.8	0.82	0.95	0.76
155	60	88.33	50	45/50 (90%)	0.96	0.84	0.86	0.95	0.8
157	60	95	53	49/53 (92%)	0.93	0.92	0.93	0.92	0.85
160	60	90	51	48/51 (94%)	1	0.88	0.9	1	0.88
161	60	83.33	47	47/47 (100%)	1	1	1	1	1
162	60	88.33	49	46/49 (94%)	0.92	0.96	0.96	0.92	0.88
163	60	93.33	52	38/52 (73%)	0.96	0.5	0.66	0.93	0.46
164	60	86.67	51	44/51 (86%)	1	0.71	0.79	1	0.72
165	60	86.67	51	42/51 (82%)	1	0.64	0.74	1	0.64
167	60	85	50	47/50 (94%)	0.96	0.92	0.93	0.96	0.88
168	60	76.67	45	44/45 (98%)	1	0.95	0.96	1	0.96
170	60	91.67	51	46/51 (90%)	0.96	0.85	0.86	0.96	0.8
173	60	90	50	40/50 (80%)	0.96	0.65	0.72	0.94	0.6
175	60	76.67	45	39/45 (87%)	1	0.71	0.8	1	0.73
177	60	86.67	48	44/48 (92%)	0.88	0.95	0.96	0.88	0.83
183	60	86.67	49	40/49 (82%)	0.96	0.68	0.74	0.94	0.63
184	60	81.67	45	44/45 (98%)	1	0.95	0.96	1	0.96
186	60	91.67	51	47/51 (92%)	0.88	0.96	0.96	0.89	0.84
187	60	90	51	48/51 (94%)	0.93	0.96	0.96	0.92	0.88
188	60	86.67	48	45/48 (94%)	0.88	1	1	0.89	0.88
189	60	98.33	55	46/55 (84%)	0.86	0.81	0.83	0.84	0.67
190	60	83.33	49	47/49 (96%)	0.96	0.96	0.96	0.96	0.92
191	60	85	50	48/50 (96%)	1	0.92	0.93	1	0.92
192	60	80	48	41/48 (85%)	1	0.7	0.78	1	0.7
194	60	86.67	51	50/51 (98%)	1	0.96	0.96	1	0.96
196	60	91.67	51	44/51 (86%)	0.77	0.96	0.95	0.8	0.73
198	60	93.33	51	46/51 (90%)	0.88	0.92	0.92	0.88	0.8
199	60	83.33	49	47/49 (96%)	0.96	0.96	0.96	0.96	0.92
202	60	86.67	48	46/48 (96%)	1	0.92	0.92	1	0.92
208	60	98.33	55	51/55 (93%)	0.93	0.92	0.93	0.92	0.85
209	60	76.67	46	45/46 (98%)	0.96	1	1	0.96	0.96

HER2 protocols

Laboratories/Fields	101	102	103	105	106	107	109	111	112	113	114	115	116	117	119	120	123	124	125	126	127	129	133	135	136	138	139	145	147	149
Clone	SP3	SP3	4B5	4B5	4B5	4B5	4B5	4B5	4B5	No Results Submitted	S3	4B5	SP3	Her2/neu (4B5_	Dako A0485	HER 2 Herceptest	4B5	4B5	4B5	SP3	4B5	Cerb b2 A0485	4B5	Polyclonal	AO485	Polyclonal - A0485	4B5	SP3	POLYCLONAL	SPC3 Mono R
Dilution	1:200	1/500	PRE	Neat	Predilute	Pre-dilute	RTU	Predilute	RTU		1/200	PREDILUTED	1/100	none	1/1000	prediluted	predilute	prÃ©-diluÃ©	predilute	1:400	PREDILUTE	1:600	Predilute	1:700	1:500	1:600	ready use	1/600	1:400	1:100
Supplier	Lab Vision	LABVISION	VENTANA	Ventana	Ventana/ Roche	Ventana	VENTANA	Ventana	VENTANA		Thermo Fisher	VENTANA	ThermoScientific	Ventana	Dako	Dako	Ventana/Roche	Ventana	Roche	Thermo	VENTANA	Dako	Ventana	Dako	Dako	Dako	Ventana	CELL MARQUE	DAKO	Thermo RM 4103-S
Ag Retrieval	CC1 Ventana	DAKO 3 IN 1 HIGH pH	CC1 36	CC1 standard	CC1 90C, 36 min	Ventana cc1 36"	CC1 MILD	CC1-36 MIN	CC1		CC1 32min	CC1	CC1 - 40 min	Cc1	HIER/CC!	40 min	CC1 mild	30 min CC1	cc1-mild	Tris buffer pH10.0 Steam	36 MINUTES	Bond ER1 low pH Retrieval Buffer	CC1 High pH	Buffer PH 6	Low	Low pH (6.0) HIER	hier CC1 30 min	CC1 32 MINS	pH6, 20 mins	PT Link pH 9 98 C 20 min
Ab Incubation Time	32 minutes	30"RT	16	32min	16min, 36C	8"	16MIN	32 MIN	16 min		16 min	24 MIN	36 min	16 min.	--	30 min	32 minutes	16 min	16 min	30 Minutes	24 MINUTES	20 min	24 minutes	15 Min	15 min	30 minutes	32 min	44 MINS	15	30 min
Ab Lot #	9103S1202D	1305H	D07696	C11145	D09098	D05831	D11261	D05831	D09098		9103S1202E	D09098	9103S1305G	D05831	--	00096371 exp 2014-05	D05831	D05831	D09098	9103S1306I	D07696	86782	D05831	81393	92075	92075	D05831	1201010C	92075	91035130
Detection	DAB	DAKO FLEX	ULTRA VIEW	DABMAP	Ultaview DAB	UltraView DAB	ULTRAVIEW DAB	Ultraview	ultraView		Ventana Optiview	IVIEW DAB	Optiview DAB	Ultraview	uutraview	Dako Autostainer Link 48	Ultraview DAB	DAB IView (biotine-steptavidin)	Ventana DAB ultraview	Dako Envision Plus	ULTRA VIEW DAB	Bond Refine Detection Kit	Ultraview	DAB BOND 3	FLEX	Polymer - Dako EnVision Flex	iview dab	XT OPTIVIEW DAB ihc v4	DAB (LEICA REFINE)	EnVision Flex Plus
Enhancement	Copper	COPPER SULPHATE	COPPER	no	none	Copper	COPPER	n/a	copper		Copper	COOPER	no	CuSo4	---	yes	Copper	non	none	None	NONE	No	none	no	no	None	no	NO	NO	Yes

Laboratories/Fields	150	151	152	153	155	156	157	159	160	161	162	164	167	170	172	175	178	179	181	186	187	188	189	190	191	194	198	199	200	202	207	209
Clone	sp3	RABBIT	4B5	4B5	4B5	No Results Submitted	4B5	No Results Submitted	A0485	Rabbit anti-human Her2 protein	4B5	4B5	A0485	ErB-2	No Results Submitted	4B5	No Results Submitted		4B5	Polyclonal	4B5	CB11	4B5	SP3 rabbit monoclonal	4B5	4B5	4B5	CB11	No Results Submitted	HER2	No Results Submitted	No Results Submitted
Dilution	1/100	1:450	Pre-diluted	ready to use	prÃ©diluÃ©		PRE DILUTED		1/700	RTU	RTU	predilute	1/1700	ready to use		predilute			Pre-diluted	1:200	Predilute	Prediluted (RTU)	RTU	1:50	rtu	Predilute	prediluted	RTU (Oracle)		RTU DAKO HERCEPTEST		
Supplier	neomarkers	DAKO	Roche-Ventana	Ventana	Ventana		VENTANA		Dako	Dako	Roche	Ventana	Dako	dako		Ventana			Ventana	DAKO	Ventana	Leica Biosystems	Ventana Medical Systems	thermofisher	roche	Ventana	Ventana-Roche	Leica		DAKO		
Ag Retrieval	cc1	HIER 1	CC1	CC1 30 minutes	CC1		YES		EDTA pH8	Herceptest epitope retrieval solution	CC1 32 min.	ultra CC1/ 36 min	CC1 (Roche)	HIER ph low		CC1			CC1 for 30 minutes	HIER 20' in Citrate buffer	CC1	ER1(25)	On-Line High pH	CC1 mild	CC1	CC1	CC1	BERS1		DAKO EPITUPE RETREIVAL SOLUTION		
Ab Incubation Time	20min	20MIN	60 minutes	12 minutes	32 min		24 MIN.		32 min	30 minutes	32 min	12 min	30 mn	30 min		12			16 minutes	15'	24.0 mins	30 mins	16 min.	40 min	16'	12 mins.	20min	30		30 MIN		
Ab Lot #	#	86782	12345	D07696	D09098		D09098		92075	20003738	C10522	D05831	86782	20003738		D10418			D05831	86781	D05831	current	D08847	9103S1301A	D06727	D09098	D05831	23508		20002273		
Detection	ultra view	BOND	iVIEW	Ultraview Dab	Ultraview dab		OPTIVIEW		DAB	Herceptest visualization reagent	UltraView DAB	UtraView	DAB	herceptest		Ultraview			Ventana Ultraview DAB	Bond Refine Detection Kit	Optiview	HER2 Oracle	UltraView	IVIEW DAB	DAB	Avidin Biotin	Ultraview	Leica Oracle Her2 Kit		HERCEPTEST DAKO KIT		
Enhancement	copper	N/A	Copper sulfate	Eltur view cooper	UV copper		DAB		No	no	-	no	copper	no		copper			Copper Sulfate	None	None	None	NA	yes	none	Copper	Copper Sulphate	NONE		NONE		

ER protocols

Labs/Fields	101	102	103	105	106	107	109	111	112	113	114	115	116	117	119	120	122	123	124	125	126	127	128	129	132	133	134	135	136	138	139	141	143	144	145	146	147
Clone	SP1	SP1	SP1	SP1	6F11	SP1	6F11	SP1	SP1	No Results Submitted	SP1	SP1	SP1	Er (sp1)	SP1	EP1	6F11	SP1	SP1	SP1	SP1	SP1	ER (SP1)	Sp 1	6F11	SP1	SP1	SP1	ER EP1	EP1	SP1	Sp1	SP1	SP1	SP1	EP1	SP1
Dilution	1:50	1/30	Pre	1:50	1:100	Pre-dilute	1/40	Predilute	RTU		1/50	PREDILUTED	RTU	none	Prediluted	prediluted	ready to use Leica	predilute	1/100	predilute	1:200	PREDILUTE	Prediluted	1:50	1:80	Predilute	Predilute	1:50	RTU	Ready-to-use	ready use	RTU - predilute	no	1:50	1/100	RTU	1:50
Supplier	Lab Vision	LABVISION	Ventana	Thermoscientific	Leica	Ventana	VECTOR	Ventana 790-4325	VENTANA		Thermo Fisher	VENTANA	Ventana	Ventana	Ventana	Dako	Nova Castra	Ventana/Roche	Cell Marque	Roche	Thermo	VENTANA	Roche	Thermo Fisher	Vector	Ventana	Ventana/Roche	Thermol Fisher	Dako	Dako	Ventana	Ventana/Roche	Confirm Ventana	Thermo Scientific	CELL MARQUE	Dako	THERMO-FISHER
Ag Retrieval	CC1 Ventana	DAKO 3 IN 1 HIGH pH	CC1 64	CC1 standard	3 min, 115C, TRIS	Ventana cc1 36"	CC1 STD (HIER)	CC1- 36 min	CC1		CC1 32min	CC1	CC1 - 64 min	Cc1	HIER/CC!	20 min	ER2 high pH 20min	CC1 mild	60 min CC1	ER2-20	Citrate pH6.0 MWPC	36 MINUTES	CC1 mild 30 minutes	Bond ER2 High pH Retrieval Buffer	Envision high pH	CC1 High pH	HIER/30 min/High pH	BUffer PH9	Low	High pH (9.0) HIER	hier CC1 30 min	HIER/Online/ 30 min/High pH	CC1 60 min	CC1 24 min	CC1 32 MINS	Flex TRS High	pH9, 20 mins
Ab Incubation Time	32 minutes	30" RT	16	1 hour	60 min	16"	44MIN	32 min	20 min		16 min	32 MIN	32 min	32 min	--	20 min	ready to use	32 minutes	32	15 min	30 minutes	32 MINUTES	30 minutes	20 mins	30 minutes	24 minutes	8 minutes	15 Min	20 min	20 minutes	32 min	8 mins	32 min	16 min@37 degrees	36 MINS	20	15
Ab Lot #	9101S1210I	1308A	D08604	9101S1210M	6022580	D08925	6018294	D06729	D06729		9101S1210L	D07686	D08925	D07686	--	10077181 exp:2014-05	22136	D08925	1316403B	D08925	9101S1305G	D01694	D07686	9101S1305F	6013974	D08925	D06729	91015120L	10075668	10084136	D09103	D06729	D04210	91015121OL	1316403F	10079669	9101S1308A
Detection	DAB	DAKO FLEX	ULTRA VIEW	Ultramap HRP	Elite vecta stain ABC	UltraView DAB	ULTRAVIEW DAB	Ultraview	ULTRA VIEW		Ventana Optiview	IVIEW DAB	Ultraview DAB	Ultraview	uutraview	Dako Autostainer Link48	DAB	Ultraview DAB	IView DAB (biotin-streptavidin)	Bond DAB Polymer Refine	Dako Envision Plus	ULTRA VIEW DAB	Ultraview Universal Dab	Bond Refine Detection Kit	Envision HRP	Ultraview	ultraView	DAB BOND 3	FLEX	Polymer - Dako EnVision FLEX	Iview dab	ultraView	I view DAB detection kit	DAB	XT OPTIVIEW DAB ihc v4	EnVision Flex Peroxydase	DAB (LEICA REFINE0
Enhancement	Copper	COPPER SULPHATE	COPPER	no	None	Copper	copper	n/a	COPPER		Copper	COOPER	no	CuSo4	---	yes	N/A	Copper		none	None	NONE	Copper	No	no	none	none	no	no	None	no	None	no	Copper	NO	Non	NO

Labs/Fields	148	149	150	151	152	153	155	156	157	159	160	161	162	163	164	165	167	168	170	172	173	175	177	178	179	180	183	184	186	187	188	189	190	191	192	194	196	198	199	200	202	207	208	209
Clone	SP1	EP1 IRO84	sp1	SP1	SP1	SP1	SP1	No Results Submitted	SP-1	No Results Submitted	SP1	EP1	SP1	SP1	SP1	sp1	SP1	SP1	Ep1	No Results Submitted	SP1	SP1	6F11	No Results Submitted	No Results Submitted	SP1	SP1	ER alpha EP1	SP1	SP1	6F11	SP1	SP1 rabbit monoclonal	SP1	SP1	SP1	sp1	6F11	6F11	No Results Submitted	6F11	No Results Submitted	6F11	EP1
Dilution	RTU	RTU	r/u	1:100	Pre-diluted	ready to use	PrÃ©diluÃ©		PRE DILUTED		No	RTU	1:100	Prediluted	predilute	nil	Kit Ventana prÃ© diluÃ©	1/200	ready to use		pre-diluted	predilute	1 : 25			RTU	predilute	RTU	1:50	Predilute	1:50	RTU	prediluted	RTU	Ready to use	Predilute	N/A	1/100	BOND RTU		1/300		1:50	Predilute
Supplier	Ventana	Dako	ventana	THERMO SCIENTIFIC	Roche-Ventana	Ventana	Ventana		VENTANA		Ventana	DAKO	Thermo Scientific	Benchmark Ventana	Ventana	ventana	Ventana (Roche)	Cell Marque	dako		Ventana	Ventana	Novocastra			VENTANA	Ventana	Dako	Thermoscientific	Ventana	Leica Biosystems	Ventana Medical Systems	ventana	roche	Ventana	Ventana	ventana	Novacastra-Leica	Leica Microsystems		VECTOR		Novacastra(leica)	Dako
Ag Retrieval	CC1 36Min	PT Link pH 9 98 C 20 min	cc1	HIER 2	CC1	CC1 30 minutes	CC1		YES		EDTA pH8	High EDTA Buffer TRIS	CC1 48 min	HIER	ultra CC1/ 36 min	cc1	CC1	High pH	HIER ph high		CC-EDTA	CCI	oui			CC1 MILD	Ultra CC1	Hi pH HIER	HIER 20' EDTA buffer	CC1	ER1(20)	On- Line high pH	CC1 mild	CC1	CC1 mild (30 min.)	CC1	NO	Diva (pH 6.2)	BERS1		EPITOPE RETREIVAL SOLUTIO PH 9.5		PH6	20 mins at 97C in High pH (EDTA) buffer and 20
Ab Incubation Time	8 min	20 min	16min	20 MIN	60 minutes	12 minutes	40 min.		24 MIN.		8 min	20 minutes	32 min	32 mn	8 min	28 min	8 mn	20 minutes	20 min		16 minutes	32	32min			16	32 minutes	30 min	15'	8 Mins	15 mins	16 min.	32	16'	16 min.	12 mins.	8 min	30min RT	20 MIN		16 MIN		1.0 HR	20 minutes
Ab Lot #	D07686	10084136	#	9101S1305F	12345	D04922	D07685		D09103		D08925	10084297	9101s1305C	D02538	D09103	d07686	D04922	1231906B	10084297		D09103	D09103	602 2582			D04210	D02538	10075668	9101S1308A	D07686	Current	NA	D07686	D06729	D07686	D08604	D04210	6018835	23449		6018294		6022580	10086340
Detection	Ultraview DAB	Envision Flex	ultraview	BOND	iVIEW	Ultra view Dab	Ultraview dab		OPTIVIEW		DAB	envision Flex	OptiView DAB	Peroxydase	UltraView	ultraview dab	DAB	Envision Flex +	Envision Flex Dako		DAB	Ultraview	Ultraview			iView DAB	Ultraview	Envision FLEX	Bond Refine Detection kit	Optiview	Bond polyer Refine Detection	UltraView	IVIEW DAB	ultraview	Ventana Ultraview DAB	Avidin Biotin	ULTRAVIEW DAB	MACH 1 Polymer	Bond Refine Detection		REFINE DETECTION KIT		Envision dual link	Polymer
Enhancement		No	copper	N/A	Copper sulphate	Ultra view copper	UV copper		DAB		No	no	-	Copper	no	nil	Copper	Rabbit Linker	no		Polymer	copper	oui			none	None	n/a	None	None	None	NA	no	none	Copper	Copper	NO	Copper Sulphate	NONE		NONE			No

PR Protocols

Labs/Fields	101	102	103	105	106	107	109	111	112	113	114	115	116	117	119	120	122	123	124	125	126	127	128	129	132	133	134	135	136	138	139	141	143	145	146	147	149
Clone	16	16	100	PgR636	PgR1294	PgR1294	16	16	100	No Results Submitted	16	100	clone 16	Pr (1E2)	16	PgR 636	16	16	100	100	PgR636	100	PR (1E2)	16	16	16	100	16	PGR 636	636	100	100	100	SP42	636	16	PgR636 IR068
Dilution	1:100	1/150	PRE	1:200	1:1500	1:50	1/100	Predilute	RTU		1/25	PREDILUTE D	1/100	none	Prediluted	Prediluted	ready to use	1/50	PrÃ©-diluÃ©	1/4 of predilute	0.25ug/ml	PREDILUTE	Prediluted	1:400	1:200	1/50	Prediulte	1:400	RTU	Ready-to-use	ready use	RTU-predilute	no	1/100	RTU	1:800	RTU
Supplier	Novocastra	LEICA	VENTANA	Dako	Dako	Dako	VECTOR	Leica	VENTANA		Novocastra	VENTANA	Leica	Ventana	Ventana	Dako	NOva Castra	Vector Laboratories	Ventana	Roche	Dako	VENTANA	Roche	Nova Castra	Vector	Vector	Ventana/Roche	Leica	Dako	Dako	Ventana	Ventana/Roche	Confirm Ventana	CELL MARQUE	Dako	NOVOCASTRA	Dako
Ag Retrieval	CC1 Ventana	DAKO 3 IN 1 HIGH pH	CC1 64	CC1 standard	3 min, 115C, TRIS	Ventana cc1 64"	CC1STD (HIER)	CC1-36 min	CC1		CC1 32min	CC1	CC1 -64 min	Cc1	HIER/CC!	20 min	ER2 - 20min	CC1 standard	30 min CC1	ER2-20	Citrate pH6.0 MWPC	36 MINUTES	CC1 mild	Bond ER2 High pH Retrieval Buffer	Envision high pH	CC1 High pH	HIER/30 min/High pH	Buffer PH9	Low	High pH (9.0) HIER	hier CC1 30 min	HIER/Online/ 30 mins/high pH	CC1 60 min	CC1 32 MINS	Flex TRS High	pH9, 20 mins	PT Link pH 9 98 C 20 min
Ab Incubation Time	32 minutes	30" RT	16	1hour	60 min	32"	32 MIN	32 min	20 min		16 min	32 MIN	48 min	16 min	--	20 min	ready to use	32 minutes	20 min	15 min	30 minutes	8 MINUTES	30 minutes	20 mins	30 minutes	32 minutes	12 minutes	15 Min	20 min	20 minutes	32 min	12 mins	32 min	52 MINS	30	15	20 min
Ab Lot #	6015355	6011269	D07381	10085019	10070965	10082389	6020167	6022635	D03286		6015355	D08442	6015355	D08442	--	10083456 exp 2015-06	19169	6020167	D07381	D09110	10078100	D02053	D06732	Z050510	6020167	6020167	D05144	1312100	10075666	10082514	D09634	D05144	D03841	1326101N	10072688	1312100	10083456
Detection	DAB	DAKO FLEX	ULTRA VIEW	Ultramap anti Ms HRP	Elite Vectastain ABC	UltraView DAB	ULTRAVIEW DAB	Ultraview	ULTRA VIEW		Ventana Optiview	IVEW DAB	ultraView DAB	Ultraview	uutraview	Dako Autostainer Link 48	Polymer reine Leica	Ultraview DAB	DAB IView (biotin-streptavidin)	Bond DAB Polymer Refine	Dako Envision Plus	ULTA VIEW DAB	Ultraview Universal Dab	Bond Refine Detection Kit	Envision HRP	Ultraview	ultraView	DAB BOND3	FLEX	Polymer - Dako EnVision FLEX	Iview dab	ultraView	I view DAB detection kit	XT OPTIVIEW DAB ihc v4	EnVision Flex Peroxydase	DAB (LEICA REFINE)	EnVision Flex Plus
Enhancement	Copper	COPPER SULPHATE	COPPER	Signalstain enhancer	None	Copper	COPPER	n/a	copper		Copper	COOPER	yes	CuSo4	---	yes	N/A	Copper		none	None	NONE	Copper	No	no	none	none	no	no	None	no	None	endogenious biotin kit	NO	None	NO	Yes

Labs/Fields	150	151	152	153	155	156	157	159	160	161	162	163	164	165	167	168	170	172	173	175	177	178	179	183	184	186	187	188	189	190	191	192	194	196	198	199	200	202	207	208	209
Clone	100	1A6	100	100	100	No Results Submitted	IE 2	No Results Submitted	100	PgR636	16	100	100	100	100	PgR 636	PgR636	No Results Submitted	100	100	pgr636	No Results Submitted	No Results Submitted	100	MxH 636	PR88	100	16	100	16	100	100	100	100	16	16	No Results Submitted	1.60E	No Results Submitted	PGR636	PgR 636
Dilution	r/u	1:200	Pre-diluted	Ready to use	prÃ©diluÃ©		PRE DILUTED		No	RTU	1:80	Prediluted	predilute	nil	Kit Ventana prÃ© diluÃ©	RTU	ready to use		pre-diluted	Predilute	1 : 25			predilute	RTU	1:100	Predilute	Prediluted (RTU)	RTU	1:50	RTU	Ready to use	Predilute	N/A	1/400	1:200		RTU		1:50	Pre dilute
Supplier	ventana	NCL	Roche-Ventana	Ventana	Ventana		VENTANA		Ventana	DAKO	Leica	Benchmark Ventana	Ventana	ventana	Ventana (Roche)	Dako	dako		Ventana	Ventana	Dako			Ventana	Dako	BIOGENEX	Ventana	Leica Biosystems	Ventana Medical Systems	novocastra	Roche	Ventana	Ventana	VENTANA	Vector Laboratories	Leica Microsystems		LEICA		Dako	Dako
Ag Retrieval	cc1	HIER 1	CC1	CC1 30 minutes	CC1		YES		EDTA pH8	High EDTA Buffer Tris	CC1 48 min	HIER	ultraCC1/ 36 min	cc1	CC1	High pH	HIER ph high		CC1-EDTA	CC1	oui			Ultra CC1	High pH HIER	HIER 20' in EDTA buffer	CC1	ER2(20)	On-line High pH	CC1 mild	CC1	CC1 mild (30 min.)	CC1	N/A	DIVA (pH 6.2)	BERS1		EPITOPRESOL PH 9.5		PH6	20 mins at 97C in High pH (EDTA) buffer and 20
Ab Incubation Time	20min	20MIN	60 minutes	24 minutes	40 min.		24 MIN.		8 min	20 minutes	32 min	32 mn	12 min	28 min	8 mn	20 minutes	20 min		16 minutes	32	32min			32 minute	30 min	15'	12.0 mins	15 mins	16 min	32	16'	16 min.	20 mins	8 MIN	30 min RT	20 MIN		16 MIN		1.0 HR	20 minutes
Ab Lot #	#	1312116	12345	D08442	D08442		D06732		D09110	10085561	6020162	C06294	D08442	d08442	D02053	10085561	10085561		D09634	D09631	10081284			D03841	10075666	MU3281213	D08442	current	NA	6015355	D05144	D09634	D02053	D03841	6020167	6011269		24640		10081824	10084980
Detection	ultraview	BOND	iVIEW	Ultraview Dab	ultraview dab		OPTIVIEW		DAB	Envision Flex	OptiView DAB	Peroxydase	UltraView	ultraview dab	DAB	Envision Flex +	Envision Flex Dako		DAB	Ultraview	Ultraview			Ultraview	Envision FLEX	Bond Refine Detection kit	Optiview	Bond polyer Refine Detection	UltraView	IVIEW DAB	DAB	Ventana Ultraview DAB	Avidin Biotin	ULTRAVIEW DAB	MACH 1 Polymer	Bond Refine Detection		REFINE LEICA DETECTION KIT		Envision dual link	Polymer
Enhancement	copper	N/A	Copper sulfate	Ultra view copper	UV copper		DAB		No	mouse linker	-	copper	no	nil	Copper	Mouse Linker	no		polymer	Copper	oui			None	Mouse Linker	None	None	None	NA	no	none	Copper	Copper	N/A	Copper Sulphate	NONE		NONE			No