

Assessors' report for cIQc Run 5: Breast module (ER, PR and HER2)

All participating laboratories received a single slide for each test. The results obtained on benign tissue only were not included for calculations of the laboratory success. Minimum concordance of 90% for both positive and negative results is suggested as "satisfactory". Minimum concordance of 95% is suggested as "optimal". The calculations for ER and PR were done using each laboratory result and following reference values:

1) *Consensus Results*: These are the results that majority of laboratories agreed upon. If the tissue core was missing for majority of laboratories, such tissue cores were excluded from calculations.

2) *Reference Laboratory*: The results of the reference laboratory for breast carcinoma markers in the United States.

3) *Reference Method*: The results obtained by the FDA approved kit for ER and PR immunohistochemistry. For HER2, the results of FISH were used instead. Kappa values were also calculated and summarized in Table 1 at the end of this document.

RUN5 was made possible due to the contribution of the Jewish General Hospital (JGH) in Montreal, Quebec. The RUN5 tissue microarray (TMA) comprising 44 different breast cancer cases from recent material from the JGH laboratory was constructed by Naciba Benlimame, PhD at the Research Pathology Facility, Segal Cancer Centre JGH under close supervision of Dr. Dragana Pilavdzic, staff pathologist at JGH and assistant professor at McGill University who is a cIQc assessor for type II immunohistochemistry (IHC).



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## Figure 1. ER garrattogram



## Figure 2. PR garrattogram



## Figure 3. HER2 garrattogram

|      | CORRECT RESULTS/CONCORDANCE (%) KAPPA-VALUE |     |                   |     |            |     |           |                   |      |           |       |                   |       |            | 2     |           |       |      |
|------|---|-----|-------------------|-----|------------|-----|-----------|-------------------|------|-----------|-------|-------------------|-------|------------|-------|-----------|-------|------|
| LAB  | Consensus                                   |     | Ref<br>Laboratory |     | Ref Method |     | Consensus | Ref<br>Laboratory | FISH | Consensus |       | Ref<br>Laboratory |       | Ref Method |       | Consensus | FISH  | LAB  |
|      | ER  | PR  | ER                | PR  | ER         | PR  | HER2      | HER 2             | HER2 | ER        | PR    | 101               | PR    | ER         | PR    | HER2      | HER2  | 1    |
| 101  | 95  | 100 | 93                | 100 | 94         | 97  | 100       | 100               | 100  | 0.880     | 1.000 | 102               | 1.000 | 0.836      | 0.943 | 1.000     | 0.947 | 101  |
| 102  | 100   | 100 | 100               | 97  | 100        | 93  | 100       | 100               | 97   | 1.000     | 0.933 | 103               | 0.933 | 1.000      | 0.865 | 1.000     | 0.930 | 102  |
| 103  | 100   | 100 | 100               | 97  | 100        | 94  | NA        | NA                | NA   | 1.000     | 0.943 | 105               | 0.945 | 1.000      | 0.881 | NA        | NA    | 103  |
| 105  | 95  | 86  | 95                | 86  | 94         | 86  | 100       | 100               | 100  | 0.870     | 0.719 | 106               | 0.734 | 0.815      | 0.703 | 1.000     | 1.000 | 105  |
| 106  | 100   | 100 | 100               | 100 | 97         | 100 | 100       | 100               | 97   | 0.939     | 1.000 | 107               | 1.000 | 0.820      | 1.000 | 1.000     | 0.942 | 106  |
| 107  | 100   | 94  | 100               | 94  | 97         | 91  | 100       | 100               | 100  | 0.939     | 0.886 | 108               | 0.886 | 0.820      | 0.830 | 1.000     | 0.944 | 107  |
| 108  | 97  | 97  | 95                | 97  | 97         | 100 | 100       | 100               | 100  | 0.941     | 0.942 | 109               | 0.994 | 0.837      | 1.000 | 1.000     | 0.947 | 108  |
| 109  | 100   | 97  | 100               | 97  | 100        | 94  | 100       | 100               | 100  | 1.000     | 0.942 | 110               | 0.994 | 1.000      | 0.885 | 1.000     | 0.942 | 109  |
| 110  | 92  | 100 | 90                | 100 | 91         | 100 | 97        | 97                | 94   | 0.829     | 1.000 | 111               | 1.000 | 0.697      | 1.000 | 0.940     | 0.879 | 110  |
| 111  | 100   | 97  | 100               | 97  | 100        | 94  | 100       | 100               | 100  | 1.000     | 0.945 | 112               | 0.947 | 1.000      | 0.885 | 1.000     | 0.942 | 111  |
| 112  | 100   | 97  | 100               | 97  | 97         | 94  | 100       | 100               | 100  | 0.934     | 0.943 | 113               | 0.943 | 0.904      | 0.876 | 1.000     | 0.945 | 112  |
| 113  | 100   | 97  | 100               | 97  | 97         | 94  | 100       | 100               | 97   | 0.939     | 0.945 | 114               | 0.945 | 0.820      | 0.881 | 1.000     | 0.940 | 113  |
| 114  | 100   | 100 | 100               | 100 | 100        | 97  | 100       | 100               | 97   | 1.000     | 1.000 | 115               | 1.000 | 0.904      | 0.937 | 1.000     | 0.937 | 114  |
| 115  | 100   | 100 | 98                | 100 | 100        | 97  | 100       | 100               | 97   | 1.000     | 1.000 | 116               | 1.000 | 1.000      | 0.943 | 1.000     | 0.947 | 115  |
| 116  | 100   | 100 | 100               | 100 | 100        | 97  | 100       | 100               | 97   | 1.000     | 1.000 | 117               | 1.000 | 0.890      | 0.944 | 1.000     | 0.942 | 116  |
| 117  | 100   | 100 | 97                | 100 | 100        | 97  | 100       | 100               | 97   | 1.000     | 1.000 | 118               | 1.000 | 0.915      | 0.943 | 1.000     | 0.941 | 117  |
| 118  | 90  | 94  | 88                | 94  | 86         | 91  | 100       | 100               | 97   | 0.772     | 0.878 | 119               | 0.878 | 0.700      | 0.819 | 1.000     | 0.942 | 118  |
| 119  | 100   | 95  | 100               | 95  | 100        | 92  | 91        | 89                | 88   | 1.000     | 0.894 | 122               | 0.897 | 1.000      | 0.832 | 0.767     | 0.719 | 119  |
| 122  | 100   | 97  | 100               | 97  | 97         | 94  | NA        | NA                | NA   | 0.939     | 0.941 | 125               | 0.943 | 0.820      | 0.885 | NA        | NA    | 122  |
| 125  | 100   | 97  | 98                | 97  | 100        | 94  | NA        | NA                | NA   | 1.000     | 0.943 | 126               | 0.944 | 0.915      | 0.889 | NA        | NA    | 125  |
| 126  | 100   | 100 | 100               | 100 | 97         | 97  | 100       | 100               | 100  | 0.939     | 1.000 | 128               | 1.000 | 0.820      | 0.944 | 1.000     | 1.000 | 126  |
| 128  | 100   | 97  | 98                | 97  | 100        | 94  | NA        | NA                | NA   | 1.000     | 0.934 | 129               | 0.937 | 0.915      | 0.873 | NA        | NA    | 128  |
| 129  | 100   | 100 | 100               | 100 | 97         | 97  | 100       | 100               | 100  | 0.939     | 1.000 | 131               | 1.000 | 0.820      | 0.943 | 1.000     | 1.000 | 129  |
| 131  | 100   | 93  | 98                | 94  | 100        | 94  | 100       | 100               | 95   | 1.000     | 0.870 | 132               | 0.875 | 0.915      | 0.811 | 1.000     | 0.904 | 131  |
| 132  | 49  | 94  | 56                | 95  | 47         | 97  | NA        | NA                | NA   | 0.239     | 0.889 | 132R              | 0.829 | 0.197      | 0.830 | NA        | NA    | 132  |
| 132R | 89  | NA  | 87                | NA  | 86         | NA  | NA        | NA                | NA   | 0.759     | NA    | 133               | NA    | 0.673      | NA    | NA        | NA    | 132R |
| 133  | 93  | 100 | 90                | 100 | 92         | 97  | 100       | 100               | 97   | 0.833     | 1.000 | 134               | 1.000 | 0.703      | 0.943 | 1.000     | 0.933 | 133  |
| 134  | 100   | 97  | 100               | 97  | 100        | 94  | 100       | 100               | 97   | 1.000     | 0.944 | 135               | 0.944 | 1.000      | 0.885 | 1.000     | 0.933 | 134  |
| 135  | 98  | 97  | 95                | 97  | 97         | 97  | 100       | 100               | 97   | 0.942     | 0.943 | 140               | 0.945 | 0.837      | 0.885 | 1.000     | 0.937 | 135  |
| 140  | 97  | 97  | 95                | 97  | 97         | 94  | 100       | 100               | 97   | 0.940     | 0.870 | 141               | 0.875 | 0.832      | 0.811 | 1.000     | 0.935 | 140  |
| 141  | 85  | 97  | 83                | 97  | 83         | 94  | NA        | NA                | NA   | 0.683     | 1.000 | 142               | 1.000 | 0.590      | 0.939 | NA        | NA    | 141  |
| 142  | 97  | 100 | 97                | 100 | 97         | 97  | NA        | NA                | NA   | 0.921     | 1.000 | 143               | 1.000 | 0.817      | 0.939 | NA        | NA    | 142  |
| 143  | 97  | 100 | 97                | 100 | 97         | 97  | NA        | NA                | NA   | 0.915     | 1.000 | 0.915             | 1.000 | 1.000      | 0.939 | NA        | NA    | 143  |

## Table 1. Run 5 descriptive statistics