Public consultation on the proposed tests for inclusion in the 2nd edition of the WHO Model List of Essential In vitro Diagnostics (EDL)

Please note:
1. Deadline to submit comments: 10 March 2019.
2. The results of this consultation will be made public, for transparency purposes.
3. Collected comments will be discussed on 18 March during the open session of the Strategic Advisory Group of Experts (SAGE IVD) meeting and will be considered by the members SAGE IVD during their deliberations.

Please state your Name: Ed Marins, MD
Organization (if applicable): Roche Molecular Systems
Country where you / your organization is based: USA
Email: Ed.Marins@roche.com
Submission date: (YY/MM/DD) 19/03/08

Kindly complete the table without modifying the format of the document - thank you.
Please note the coding for Comment type: ED = Editorial / TE = Technical; PHC=Primary Health Care, HCCL=Health Care Facilities with Clinical Laboratories.
There are five sections, one for general comments and then each of the four sections, please submit your comment to the appropriate section to facilitate.

ENTER GENERAL COMMENT(S):

The Specimen type and Assay format should be generally described to allow countries to use solutions they already have in place and to also favour competition without benefiting any particular manufacturer.
### I. COMMENTS RELATED TO CHANGES TO EXISTING ENTRIES OF THE CURRENT ESSENTIAL DIAGNOSTICS LIST

<table>
<thead>
<tr>
<th>Tab Name (PHC, PHC by Disease, HCCL, HCCL by disease)</th>
<th>Line no.</th>
<th>Comment type</th>
<th>Current Entry</th>
<th>Proposed change / suggested text</th>
<th>Supporting comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCCL by Disease</td>
<td>71-73</td>
<td>TE</td>
<td>Specimen type – Dried blood spot</td>
<td>Specimen type – “Dried blood spot (whole blood or plasma)”</td>
<td>Currently available technology allows for either dried whole blood spot or dried plasma spot to be used for monitoring response to HIV antiviral treatment. The proposed change clarifies this aspect.</td>
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<tr>
<td>HCCL by Disease</td>
<td>105 - 110</td>
<td>ED</td>
<td>Assay format – Cartridge-based NAT</td>
<td>Delete “cartridge-based” and state as only “NAT”</td>
<td>Given availability of various NAT technologies and to be consistent throughout EDL, the assay category could be generally described as “NAT,” inclusive of cartridge-based or non-cartridge based conventional PCR. This would allow countries to use solutions they already have in place, or other PCR-based options.</td>
</tr>
<tr>
<td>HCCL by Disease</td>
<td>111-113</td>
<td>ED</td>
<td>Assay format – Molecular LPA</td>
<td>Revise Assay format to “NAT”</td>
<td>To be consistent throughout EDL, the assay category could be generally described as “NAT,” inclusive of Molecular LPA. This would allow countries to use solutions they already have in place, or other PCR-based options that are not LPA based.</td>
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</tbody>
</table>
# I. COMMENTS RELATED TO CHANGES TO EXISTING ENTRIES OF THE CURRENT ESSENTIAL DIAGNOSTICS LIST

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<th>Classification</th>
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Please add rows as necessary (with "copy and paste" empty rows)

# II. COMMENTS RELATED TO FULL SUBMISSIONS TO THE SECOND EDITION OF THE ESSENTIAL DIAGNOSTICS LIST

<table>
<thead>
<tr>
<th>Submission ID</th>
<th>Section of review</th>
<th>Comments</th>
<th>Classification</th>
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</table>

Please add rows as necessary (with "copy and paste" empty rows)

# III. COMMENTS RELATED TO SUGGESTED ADDITIONS OF GENERAL PATHOLOGY TESTS
### IV. COMMENTS RELATED TO SUGGESTED ADDITIONS OF THERAPEUTIC DRUG MONITORING TESTS

<table>
<thead>
<tr>
<th>Page no.</th>
<th>Line no.</th>
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<th>Current Text</th>
<th>Proposed change / suggested text</th>
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The WHO EDL secretariat is thankful for your input.