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# PEER-REVIEW REPORT

**Name of journal:** *World Journal of Virology*

**Manuscript NO:** 86345

**Title:** Performance evaluation of NeuMoDx 96 system for Hepatitis B & C viral load

**Provenance and peer review**: Unsolicited Manuscript; Externally peer reviewed

**Peer-review model:** Single blind

**Reviewer's code:** 05457585
**Position:** Peer Reviewer
**Academic degree:** MD, MSc, PhD
**Professional title:** Assistant Professor
**Reviewer's Country/Territory:** Bangladesh
**Author's Country/Territory:** India

**Manuscript submission date:** 2023-06-21

**Reviewer chosen by:** AI Technique

**Reviewer accepted review:** 2023-06-21 18:29

**Reviewer performed review:** 2023-06-21 19:21

**Review time:** 1 Hour

| | |
|---|---|
| **Scientific quality** | [ ] Grade A: Excellent [ ] Grade B: Very good [Y] Grade C: Good<br>[ ] Grade D: Fair [ ] Grade E: Do not publish |
| **Novelty of this manuscript** | [ ] Grade A: Excellent [Y] Grade B: Good [ ] Grade C: Fair<br>[ ] Grade D: No novelty |
| **Creativity or innovation of this manuscript** | [ ] Grade A: Excellent [Y] Grade B: Good [ ] Grade C: Fair<br>[ ] Grade D: No creativity or innovation |

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|---|---|
| **Scientific significance of the conclusion in this manuscript** | [ ] Grade A: Excellent [ Y] Grade B: Good [ ] Grade C: Fair [ ] Grade D: No scientific significance |
| **Language quality** | [ ] Grade A: Priority publishing [ ] Grade B: Minor language polishing [ Y] Grade C: A great deal of language polishing [ ] Grade D: Rejection |
| **Conclusion** | [ ] Accept (High priority) [ ] Accept (General priority) [ ] Minor revision [ Y] Major revision [ ] Rejection |
| **Re-review** | [ Y] Yes [ ] No |
| **Peer-reviewer statements** | Peer-Review: [ ] Anonymous [ Y] Onymous |
| | Conflicts-of-Interest: [ ] Yes [ Y] No |

**SPECIFIC COMMENTS TO AUTHORS**

Major Comments: 1. Are there controversies in this field? What are the most recent and important achievements in the field? In my opinion, answers to these questions should be emphasized. Perhaps, in some cases, novelty of the recent achievements should be highlighted by indicating the year of publication in the text of the manuscript. 2. The results and discussion section is very weak and no emphasis is given on the discussion of the results like why certain effects are coming in to existence and what could be the possible reason behind them? 3. Conclusion: not properly written. 4. Results and conclusion: The section devoted to the explanation of the results suffers from the same problems revealed so far. Your storyline in the results section (and conclusion) is hard to follow. Moreover, the conclusions reached are really far from what one can infer from the empirical results. 5. The discussion should be rather organized around arguments avoiding simply describing details without providing much meaning. A real discussion should also link the findings of the study to theory and/or literature. 6. Spacing, punctuation marks, grammar, and spelling errors should be reviewed thoroughly. I found so many typos throughout the manuscript. 7. English is modest. Therefore, the

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authors need to improve their writing style. In addition, the whole manuscript needs to be checked by native English speakers.

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**Reviewer's code:** 00052947
**Position:** Peer Reviewer
**Academic degree:** MD
**Professional title:** Director, Professor
**Reviewer's Country/Territory:** Germany
**Author's Country/Territory:** India

**Manuscript submission date:** 2023-06-21

**Reviewer chosen by:** AI Technique

**Reviewer accepted review:** 2023-06-21 13:35

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**Review time:** 5 Days and 1 Hour

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|---|---|
| **Scientific quality** | [ ] Grade A: Excellent [ ] Grade B: Very good [Y] Grade C: Good<br>[ ] Grade D: Fair [ ] Grade E: Do not publish |
| **Novelty of this manuscript** | [ ] Grade A: Excellent [Y] Grade B: Good [ ] Grade C: Fair<br>[ ] Grade D: No novelty |
| **Creativity or innovation of this manuscript** | [ ] Grade A: Excellent [ ] Grade B: Good [Y] Grade C: Fair<br>[ ] Grade D: No creativity or innovation |

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| **Conclusion** | [ ] Accept (High priority) [ ] Accept (General priority) [ ] Minor revision [ Y] Major revision [ ] Rejection |
| **Re-review** | [ Y] Yes [ ] No |
| **Peer-reviewer statements** | Peer-Review: [ Y] Anonymous [ ] Onymous |
| | Conflicts-of-Interest: [ ] Yes [ Y] No |

**SPECIFIC COMMENTS TO AUTHORS**

General comment The availability and performance of rapid and accurate tests for HBV and HCV levels in serum samples is of high clinical and economic importance. The authors compared the relatively new, rapid, and affordable test NeuMoDx96 with the well-established, but slow and expensive COBAS test from Roche. They tested 186 patient samples with HBV or HCV infection. • Unfortunately, the preselected patients with known results from the Roche test are insufficiently described. Thus, it is not clear whether only easy to diagnose cases or difficult cases were also included. An independent determination of the limit of detection is missing. • The formal statistics of the data looks at the first glance correct, but a closer look reveals inconsistencies (points 7-9). • The text contains several inaccuracies which need to be corrected. Specific points 1. Abstract. “For HBV, out of 99 samples, 49 (49.49%) were DNA positive. For HCV out of 87 samples, 39 (44.82%) were RNA positive.” The authors should state how the diagnosis of HBV and HCV infection was established. Easiest would be: “Out of 99 HBsAg positive samples 49 (49.9%) were DNA positive, out of 87 anti-HCV positive samples were 39 (44.8%) were RNA positive.” However, the role of anti-HBc should not

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have been neglected. 2. Introduction. “Moreover, viral hepatitis accounts for around 96% of mortality in low and middle income countries.” But there is one word missing: hepatitis mortality. According to reference 1, WHO writes: The report focuses on hepatitis B and C, which are responsible for 96% of all hepatitis mortality. 3. Introduction. The statement on the sensitivity and specificity of the new test are unsatisfactory. Does, e.g., 95.6% specificity mean that 4.3% of the positives are false positive? Or was the comparator assay false negative? 4. Materials and Methods. The authors forgot to report the selection criteria for HBV and HCV, see also point 1. Figure 1 is not helpful in this respect. 5. Table 1 should show the clinical data for HBV and HCV patients separately and somewhere in the legend or a footnote it should be described what was the basis for the diagnosis HBV and HCV. The description in the results should also be extended. a. Were the cases exclusively chronic HBV infections (CHB)? b. How many had active hepatitis, how an inactive HBV infection? ”The data of table 1 are not helpful. “Non-cirrhotic” may still be an active CHB. c. Were any occult HBV infections included? d. How many cases had received an antiviral HCV therapy? 6. Methods. Comparison of assays 1 and 2. The technical data of the two tests are well compiled in the text, but a well-designed table would allow for better comparison. 7. Results. The data of table 2a and fig. 2a on HBV DNA do not agree. a. The table shows three cases with >10E6 IU/ml HBV DNA for assay 1 and two cases for assay 2. But the figure shows 6 dots for log IU/ml >6 for assay 1, and 5 dots for assay 2. b. The numbers seem to agree for the mid-range of log IU/ml 3-6 for both assays. c. I could not exactly count the dots for the low range 10-10E3, but there are less than 31 or 29 dots in the figure than the 31 cases of the table 2a. d. The dot at zero in fig. 2a cannot be meaningful, because the LOD of assays is 0.9 or 1.5 and not 0 log IU/ml (i.e., 1 IU/ml). e. The main text must be revised or must explain the inconsistency. f. I could not find table 2b in my file. 8. Correlation between the two assays in detection of HBV viral load. “Assay 1 and Assay 2

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quantified 99 samples …". a. This statement is wrong because only 49 samples were positive. A negative result cannot be quantified. b. The correlation between the two assays is indeed very good, but fig. 2a and b suggest that assay 2 slightly overestimates low values <4 log IU/ml and underestimates higher values in comparison to assay 1, as suggested also by the medians. 9. Correlation between the two assays in detection of HCV viral load. The authors write: "… a very good correlation (R2= 0.957) was observed between the two assays (Fig. 3a)." However, the correlation was not as good as with HBV. Fig. 3a and 3b identify 3 outliers with far too low values in the Roche assay. Thus, the correlation is at best good, not very good. 10. Performance of the NeuMoDX 96 in different genotypes of HBV& HCV. Since the author have the sequence of the HBV and HCV samples, the subgenotypes could also be identified. E.g., HBV subgenotypes A1 and A2 are very different and may occur in India.