SARS-CoV-2 MOLECULAR Acceptance Review Summary – EUA203041

We have performed an administrative content review of this file. The following information in Tables 1 and 2 below is not intended to serve as a comprehensive review. Items highlighted in YELLOW below were found to be incomplete in the EUA request.

Administrative Information	
Document Number:	EUA203041
Device Name:	PCRmon
Sponsor Name:	Richard Rouse
Sponsor's Contact:	rjdrouse@htsresources.com

EUA Request - Submission Content Review Checklist

TABLE 1 – General Device EUA Content	**Yes**	**No**	**N/A**
The product is a device or a combination product with a device constituent part	☒	☐	☐
The submission is written in English;	☒	☐	☐
A description of the product and its intended use (e.g., identification of the serious or life-threatening disease or condition for which the product may be effective; where, when, and how the product is anticipated to be used; and/or the population(s) for which the product may be used);	☐	☒	☐
A description of the product's FDA approval status (e.g., whether the product is unapproved or whether it is approved but the EUA is for an unapproved use); whether the product or intended use is under an investigational application (e.g., if an IND/IDE is in effect or has been submitted; whether the product is approved in a foreign country for either the proposed use or another use; information on the use of the medical product by either a foreign country or an international organization (e.g., the World Health Organization (WHO)); The submission may identify prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.) or state that there were no prior submissions for the subject device;	☐	☒	☐
The need for the product, including identification of any approved alternative product(s) and their availability and adequacy for the proposed use, and the unmet need(s) the EUA would address;	☐	☒	☐
For device types with a published interactive review template, information was provided related to each of the study types requested in the submission (See Table 2 below)	☐	☐	☒
Product's mechanism(s) of action to diagnose, treat, or prevent the disease or condition underlying the request was described, including;			
a. Evidence from human experience relevant to assessing activity, effectiveness, and dosing (e.g., in published case reports, uncontrolled trials, controlled trials, and any other relevant human use experience);	☐	☐	☒
b. Data on activity or effectiveness in animals that would contribute to understanding potential effects in humans, including but not limited to any animal efficacy studies available for products being developed under the Animal Rule;	☐	☐	☒
c. Well-organized study reports that provide a complete assessment and analysis, including any statistical analyses, of available safety and effectiveness data and an interpretation of the findings. If final study reports are not yet available, any available interim study reports should be provided and clearly identified as such;	☐	☒	☐

TABLE 1 – General Device EUA Content	Yes	No	N/A
d. Source data for clinical studies, nonclinical laboratory studies, and any animal studies that contribute to assessing activity or effectiveness of the product in the treatment of the underlying disease or condition or a closely related disease or condition, such as case report tabulations for key studies; case report forms for all patients who died during the clinical studies and for all persons who did not complete the study due to an adverse event, regardless of causality; relevant reports in the published literature; and translations of source materials that are in a language other than English.	☐	☒	☐
e. For IVDs, device performance data to support the intended use such as analytical sensitivity and analytical specificity, and data from testing fresh, contrived, banked or archived specimens. (see Table 2 below)	☐	☒	☐
A discussion of risks and benefits, including available information concerning the threats posed by the CBRN agent(s) involved (discussed in more detail below within this section) including: (select all that apply)	☐	☐	☒
a. Measures taken to mitigate risk or optimize benefit;	☐	☐	☒
b. Limitations, uncertainty, and data gaps;	☐	☐	☒
c. A description of circumstances, if any, under which the product should not be used (e.g., contraindications); and	☐	☐	☒
d. To the extent known, information concerning the threats posed by the CBRN agent(s) (actually or potentially) involved, and anticipated response and operational considerations that may be relevant to an assessment of risks and benefits.	☐	☐	☒
Information on chemistry (as applicable), manufacturing, and controls; a list of each site where the product, if authorized, is or would be manufactured, and the current CGMP status of the manufacturing site(s);	☐	☒	☐
Information about the quantity of finished product on hand and the surge capabilities of the manufacturing site(s);	☐	☒	☐
Information comparable to an FDA-approved package insert or instructions for use; drafts of the "Fact Sheets" to be furnished to health care professionals or authorized dispensers and recipients of the product, which typically are part of pre-EUA discussions; and a discussion of the feasibility of providing such information in an emergency;	☐	☒	☐
If seeking an extension of a product's labeled expiration date, any available information in support of such an extension (e.g., information on product stability such as test results; prior and anticipated storage and handling conditions; the lots, batches, or other units affected; any prior expiration date extensions; and for medical devices, an explanation of labeled expiration date, such as whether the inclusion of such information was based on a premarket requirement, requirements of another regulatory body, or a business decision);	☐	☐	☒

TABLE 2 – IVD Template Content - MOLECULAR	Yes	No	N/A
Target(s) detected described?	☐	☒	☐
Specimen type(s) indicated? (e.g., NP: ☐ OP: ☐ Nasal: ☐ Sputum: ☐ Saliva: ☐ Other: ☐)	☐	☒	☐
Setting of use described, including in the instructions for use?	☐	☒	☐

TABLE 2 – IVD Template Content - MOLECULAR	Yes	No	N/A
(e.g., POC: ☐ Home collection ☐ Home use: ☒ Central Lab: ☐)			
Clinical data as described in the appropriate[6] Molecular Template are provided that address all claimed matrices, OR justification for equivalent[7] alternate approaches to clinical validation provided.	☐	☒	☐
☒**COMMENT**: No Molecular Template was submitted, only a MS Word document with a description of the candidate instrument. No data or study designs were provided.			
Matrix equivalency data as described in the Molecular Template, including a clear and complete study protocol, are provided and complete.	☐	☒	☐
Interference assessment as described in the Molecular Template, is provided and complete.	☐	☒	☐
Interference data as described in the Molecular Template, including a clear and complete study protocol, are provided and complete.	☐	☒	☐
Cross reactivity data as described in the Molecular Template, including a clear and complete study protocol, are provided and complete.	☐	☒	☐
Data, collected as described in the Molecular Template, to support the assay's Limit of detection as well as a clear and complete study protocol, are provided and complete.	☐	☒	☐
Data to support Point of Care (POC) claims, as well as a clear and complete study protocol, are provided and complete.	☐	☒	☐
☒**COMMENT**: In addition, there was no usability study provided, or study design suggested.			
Are external positive and negative control provided with the test kit or, if not provided, specifically identified in the instructions for use?	☒	☐	☐
Were the claimed external positive and negative control materials validated in the analytical and clinical studies?	☐	☒	☐
Is specimen stability information provided?	☐	☒	☐
Is the labeling compliant with relevant parts of 21 CFR 809.10? Most authorized IVD EUAs have required compliance with the following parts of 21 CFR 809.10: the intended use statement (21 CFR 809.10(a)(2), (b)(2)); adequate directions for use (21 U.S.C. 352(f)), (21 CFR 809.10(b)(5), (7), and (8)); any appropriate limitations on the use of the device including information required under 21 CFR 809.10(a)(4); and any available information regarding performance of the device, including requirements under 21 CFR 809.10(b)(12)	☐	☒	☐
ADDITIONAL COMMENTS: The only document submitted was a description of a thermal block to perform PCR or LAMP assays. No validation of the device was provided. The submission should include a description of the diagnostic device (i.e. assay and instrument) and data to support the use of the assay on that instrument. **Further, while the submission suggests home use, the complexity of the steps and possibly required reagents (proposed EUA CDC assay) suggests that the system might be more appropriate for laboratories that meet the requirements to perform high complexity tests.**	☒	☐	☐

[6] Multiple molecular SARS-CoV-2 templates may be found at https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas