**MUFSC Validation Review Check sheet**

**VALIDATION REVIEW CHECKSHEET**

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| --- |
| Validation Title: |

***Meet Forensic and Databasing QAS Standards: most current version.***

|  |  |
| --- | --- |
| For internal validation studies | Yes/No  (if “No” use comments) |
| Have internal validation studies been documented and summarized? |  |
| Include known and non-probative evidence samples or mock evidence samples? |  |
| Include reproducibility and precision studies? |  |
| Include sensitivity and stochastic studies? |  |
| Include mixture studies? |  |
| Include a contamination assessment? |  |
| Interpretation guidelines written. |  |

Developmental Validation Location:

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| --- | --- |
| For change in detection platform | Yes/No  (if “No” use comments) |
| Have internal validation studies been documented and summarized? See list above. |  |

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| --- | --- |
| For modified procedures | Yes/No  (if “No” use comments) |
| Been evaluated by comparison with the original procedures using similar DNA samples? |  |
| Conducted a performance check on each additional or modified critical instrument? |  |
| Evaluated software upgrades through a performance check? |  |

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| ***Additional Comments / Recommendations:*** |
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| Technical Leader approval | |
| Signature: | Date: |

***Quality Assurance:***

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| Have procedures been written and made official? |  |
| Have worksheets been created and made official? |  |

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| ***Additional Comments / Recommendations:*** |
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| Quality Manager | |
| Signature: | Date: |

***Training:***

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| Have a plan for training laboratory staff? |  |

***See training checksheet***

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| ***Additional Comments / Recommendations:*** |
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| Training Officer | |
| Signature: | Date: |

Personnel Acknowledgement

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| **Date** | **Employee** | **Signature** |
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The validation listed has been reviewed and the contents therein approved.

**Methods and reporting from early WW work at Marshall**

**Summary methods used in dormitory testing from Oct. 2020 through April 2021 (and ongoing)**

Automatic WW samplers are set up in the dormitories the night before sampling period.

Samples are retrieved sometime after 12 noon after composite sampling period of 5 hours (7am-12pm).   
When sample is picked up, tubing is washed and sterilized using the sampler’s peristaltic pump following USGS reference. (Quantifying Viruses and Bacteria in Wastewater—Results, Interpretation Methods, and Quality Control, 2011)  
70mL subsamples of wastewater is processed via AlOH3 precipitation and concentrated down to 0.350mL (200:1 concentration method – Randazzo method in references). This material is further processed to protect the DNA/RNA targets and/or to prepare the sample for RNA extraction with cell lysis solution. Samples are always kept on ice and are stored at -70degC when not being processed. About once per week, samples are transported to MUFSC (forensic science DNA analytical lab).   
  
MUFSC procedure:

Samples received at MUFSC are immediately placed in a secure -70o C storage. Prior to extracting, samples are thawed at ~30oC.  If necessary, ASL/ AVL Buffer is added to the appropriate sample, otherwise the samples are directly extracted using Qiagen’s Virus Mini kit v2.0 on the EZ1 Advanced XL.  Samples are eluted in buffer AVE (RNase free water and sodium azide). Samples are transported via hand delivery to the Kopp Hall (SOP) using a -20oC sample transport carrier (buildings are adjacent therefor a vehicle is not used).   
Note: All disposable items in contact with the sample during the extraction process are discarded in biohazard waste.  All work is performed in a certified biosafety cabinet specific for RNA extraction.  Appropriate BSL-2 PPE is always worn in the extraction laboratory.

MU pharmacy procedure:

Total RNA in RNase free water is transported to the Kopp Hall (Pharmacy) and stored at -70oC   Replicate samples were quantified using Quantitative real-time PCR using Promega GoTaq® Probe 1- Step RT-qPCR System and primer set 2019-nCov CDC EUA Kit.

**Summary results from dormitory testing from Oct. 2020 through April 2021**

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| --- | --- | --- | --- | --- |
| **Sample ID** | **Date Collected (sample from 7am-1pm in 2020, 7am-12pm begining 2021)** | **Origin of Sample(Towers East, Towers West, Wellman)** | **Sample Appearance 0=clean water, 1=clear, 5=very turbid/brown** | **detected or not detected as judged by qPCR reaction in MU School of Pharmacy and/or Forensic Science (sarscov2, FDA EUA test primer sets)** |
| **g** | 10/13/2020 | TTE | 3 | **detected** |
| **h** | 10/16/2020 | TTW | 1 | not detected |
| **i** | 10/20/2020 | Wellman | 4.5 | not detected |
| **J** | 10/21/2020 | Wellman | 3 | not detected |
| **k** | 10/22/2020 | TTE | 4 | not detected |
| **l** | 10/23/2020 | TTW | 1.5 | not detected |
| **m** | 10/27/2020 | TTW | 2 | not detected |
| **n** | 10/28/2020 | TTE | 2 | not detected |
| **o** | 10/30/2020 | TTE | 3.5 | not detected |
| **p** | 11/3/2020 | Wellman | 4.5 | **detected** |
| **q** | 11/4/2020 | TTE | 4 | not detected |
| **r** | 11/5/2020 | TTE | 2.5 | not detected |
| **s** | 11/6/2020 | TTE | 3 | not detected |
| **t** | 11/10/2020 | TTE | 3.5 | **detected** |
| **u** | 11/10/2020 | TTW | 1 | not detected |
| **v** | 11/11/2020 | TTE | 1 | **detected** |
| **w** | 11/11/2020 | TTW | 1 | not detected |
| **x** | 11/12/2020 | TTE | 4.3 | not detected |
| **y** | 11/12/2020 | TTW | 3 | not detected |
| **z** | 11/13/2020 | TTW | 2 | not detected |
| **aa** | 11/17/2020 | TTW | 1 | not detected |
| **ab** | 11/17/2020 | TTE | 2.7 | not detected |
| **ac** | 11/18/2020 | TTW | 1.5 | not detected |
| **ad** | 11/18/2020 | TTE | 3 | not detected |
| **ae** | 11/19/2020 | TTW | 2.5 | not detected |
| **af** | 11/19/2020 | TTE | 1.5 | **detected** |
| **ag** | 11/20/2020 | TTW | 0.5 | not detected |
| **ah** | 11/20/2020 | TTE | 2.7 | not detected |
| **ai** | 12/1/2020 | TTE | 4 | not detected |
| **aj** | 12/2/2020 | TTW | 1 | **detected** |
| **ak** | 12/2/2020 | TTE | 2 | **detected** |
| **al** | 12/3/2020 | TTE | 3 | **detected** |
| **am** | 12/4/2020 | TTW | 2.5 | **detected** |
| **an** | 12/10/2020 | TTE | 2 | not detected |
| **ao** | 12/11/2020 | TTW | 1.3 | **detected** |
| **ap** | 12/22/2021 | TTW | 1.1 | **detected** |
| **aq** | 1/7/2021 | TTE | 1.5 | not detected |
| **ar** | 1/12/2021 | TTE | 3 | not detected |
| **as** | 1/21/2021 | TTE | 3 | not detected |
| **at** | 1/21/2021 | TTW | 3 | **detected** |
| **au** | 1/26/2021 | TTE | 2.5 | not detected |
| **av** | 1/28/2021 | TTW | 0.5 | not detected |
| **aw** | 1/28/2021 | TTE | 2.5 | not detected |
| **ax** | 2/2/2021 | TTE | 1.5 | not detected |
| **ay** | 2/2/2021 | TTW | 2 | not detected |
| **az** | 2/4/2021 | TTW | 1.5 | not detected |
| **ba** | 2/4/2021 | TTE | 1.5 | not detected |
| **bb** | 2/9/2021 | TTW | 2.5 | not detected |
| **bc** | 2/9/2021 | TTE | 3 | not detected |
| **bd** | 2/11/2021 | TTE | 3 | **detected** |
| **be** | 2/11/2021 | TTW | 2 | not detected |
| **bf** | 2/23/2021 | TTE | 4 | **detected** |
| **bg** | 2/23/2021 | TTW | 2.8 | not detected |
| **bh** | 2/25/2021 | TTW | 2.8 | not detected |
| **bi** | 2/25/2021 | TTE | 3 | **detected** |
| **bj** | 3/2/2021 | TTW | 1 | not detected |
| **bk** | 3/2/2021 | TTE | 2.5 | not detected |
| **bl** | 3/4/2021 | TTW | 2.5 | not detected |
| **bm** | 3/4/2021 | TTE | 1.5 | not detected |
| **bn** | 3/9/2021 | TTE | 2.5 | **detected** |
| **bo** | 3/9/2021 | TTW | 2 | not detected |
| **bq** | 3/16/2021 | TTE | 2.5 | not detected |
| **br** | 3/16/2021 | TTW | 3.5 | not detected |
| **bs** | 3/18/2021 | TTE | 2.5 | **detected** |
| **bt** | 3/18/2021 | TTW | 1 | not detected |
| **bu** | 3/22/2021 | TTE | 2 | not detected |
| **bv** | 3/22/2021 | TTW | 1.5 | not detected |
| **bw** | 3/25/2021 | TTW | 3 | not detected |
| **bx** | 3/25/2021 | TTE | 3 | not detected |
| **by** | 3/30/2021 | TTW | 2 | not detected |
| **bz** | 3/30/2021 | TTE | 2 | not detected |
| **ca** | 4/6/2021 | TTE | 3 | not detected |
| **cb** | 4/8/2021 | TTW | 1 | not detected |

**References used in SOW for MU\_WW\_DHHR spring 2021 :**

**WW sampling and testing methods**

Virology Research in early days of COVID19, basis for MU current methods

Medema, Gertjan, et al. Presence of SARS-Coronavirus-2 RNA In Sewage and Correlation with Reported Covid-19 Prevalence in The Early Stage of The Epidemic in The Netherlands. Environ. Sci. Technol. Lett. 2020, 7, 511-516.   
 pubs.acs.org/doi/10.1021/acs.estlett.0c00357.

Randazzo, Walter, et al. SARS-Cov-2 RNA In Wastewater Anticipated Covid-19 Occurrence in A Low Prevalence Area. Water Research. 2020, 181, 115942.www.ncbi.nlm.nih.gov/pmc/articles/PMC7229723/.

Virology Research Using TaqMan Gene Expression Assays and Arrays. Thermo Fisher Scientific - US, [www.thermofisher.com/us/en/home/life-science/pcr/real-time-pcr/real-time-pcr](http://www.thermofisher.com/us/en/home/life-science/pcr/real-time-pcr/real-time-pcr) applications/geneexpression-using-real-time-pcr/virology-research.html.

Quantifying Viruses and Bacteria in Wastewater

Results, Interpretation Methods, and Quality Control By Donna S. Francy, Erin A. Stelzer, Rebecca N. Bushon, Amie M.G. Brady, Brian E. Mailot, Susan K. Spencer, Mark A. Borchardt, Ashley G. Elber, Kimberly R. Riddell, and Terry M. Gellner. Prepared in cooperation with Ohio Water Development Authority and City of Delphos, Ohio Scientific Investigations Report 2011–5150 U.S. Department of the Interior U.S. Geological Survey​  
  
**collaboration**  
WVU site – Tim Driscoll  
 https://biology.wvu.edu/faculty-and-staff/faculty/tim-driscoll

**reporting**  
NWSS reporting site.   
 [National Wastewater Surveillance System (NWSS) – a new public health tool to](https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/wastewater-surveillance.html)  understand COVID-19 spread in a community | CDC  
 https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/wastewater- surveillance.html

LIMS/Q-bench   
 https://qbench.net/

**validation**  
ISO 17025 standards   
 https://www.iso.org/ISO-IEC-17025-testing-and-calibration-laboratories.html  
  
  
**viral panels**  
[Virology Research using TaqMan Gene Expression Assays and Arrays | Thermo Fisher Scientific - US](https://www.thermofisher.com/us/en/home/life-science/pcr/real-time-pcr/real-time-pcr-applications/gene-expression-using-real-time-pcr/virology-research.html)

https://www.thermofisher.com/us/en/home/life-science/pcr/real-time-pcr/real-time-pcr- applications/gene-expression-using-real-time-pcr/virology-research.html

**non-standard testing activities**   
 SEM sandwich assay on swab PPE analysis with SEM

Assessment of N95 and K95 respirator decontamination: fiber integrity, filtration efficiency, and dipole charge density. Wonjun Yim, Diyi Cheng, Shiv Patel, Rui Kui, Ying Shirley Meng, and Jesse V. Jokerst  
 <https://www.medrxiv.org/content/10.1101/2020.07.07.20148551v1.full.pdf>

Special Issue on COVID-19 Aerosol Drivers, Impacts and Mitigation (VII) Aerosol and Air Quality Research, 20: 2309–2317, 2020.  
 Addressing COVID-19 Spread: Development of Reliable Testing System for Mask Reuse Haoxian Lu, Dawen Yao, Joanne Yip, Chi-Wai Kan, Hai Guo

<https://aaqr.org/articles/aaqr-20-06-covid-0275.pdf>