New Mexico Medical Advisory Team (MAT) Assessment

MAT Workgroup Name: Clinical Care **Date:** June 3, 2020

Question or request:
Specimen collection: Please provide an updated advisory for the various methods of specimen collection for COVID-19 testing (-Saliva-Sputum-Oropharyngeal Swab-Nasal Swab-Nasopharyngeal Swab) including the sensitivity and specificity impact of each if known, recommended use in various populations/environments, and the general availability and FDA approval of newer methods. Please address self-collection.

Recommendation/s in bullet form: Recommendations below are in preferential order. Please see the detailed table attached for additional information on each specimen collection method.

1. **Nasopharynx (NP)**
   a. The single-source specimen that is most sensitive in most situations.
   b. Should be first choice if supplies available in most settings where highest sensitivity is desired.
   c. Note: One important exception is in advanced disease, greater than 8 days since symptom onset in acutely ill patients, where a bronchoalveolar lavage (BAL) or tracheal aspirate may be indicated/more sensitive when NP specimen is negative and/or COVID-19 suspicion is high.

2. **Nasal/Anterior Nares (Provider or Observed Self-Collection)**
   a. Slightly less sensitive than NP source, but an acceptable alternative in most settings.
   b. Specimen must be collected from both nares using the same swab.

3. **Bronchoalveolar Lavage (BAL)/Tracheal Aspirate**
   a. See above.

<u>Other Specimen Collection Methods Not Currently Recommended</u>
Unless in cases of crisis-level on hand of specimen collection types 1-3 above.

4. **Oropharynx (OP)**
   a. Less sensitive than nasal in most settings.
   b. Not currently recommended in most settings unless NP/nasal swab availability is extremely limited.

5. **Combination sources (NP/OP or OP/mid-turbinate nasal (MT))**
   a. May increase sensitivity, but not generally recommended due to increased swab resource consumption.

6. **Sputum**
   a. Not currently recommended due to limited performance data.

7. **Saliva**
   a. Not currently FDA approved. May have value in the future; studies are underway.

8. **Self-Collection**
   a. Only FDA approved for specific collection devices and testing through LabCorp.
   b. Must be supervised on-site by a healthcare professional and only for MT, Nasal/Anterior Nares, or OP specimen types.

Assessment: PCR-based testing to detect the SARS-CoV-2 virus from respiratory specimens generally has very high sensitivity and is used to detect active infection, assuming a good sample was obtained. A nasopharyngeal is the preferred choice for swab-based SARS-CoV-2 testing. If a nasopharyngeal swab is not available, a nasal swab, oropharyngeal swab, mid-turbinate swab may be collected.

Initial Testing Guidance

Patient status	Presentation	Perform PCR
• Hospitalized patients • Healthcare facility workers, workers in congregate living settings, and first responders **with** symptoms • Residents in long-term care facilities or other congregate living settings, including prisons and shelters, **with** symptoms • Persons identified through public health cluster and selected contact investigations • Persons **with** symptoms of potential COVID-19 infection, including: fever, cough, shortness of breath, chills, muscle pain, new loss of taste or smell, vomiting or diarrhea and/or sore throat	Symptomatic (<6 Days of symptoms)	**Yes** ***Preferred Specimen:*** *Nasopharyngeal, Nasal, Oropharyngeal* *Acceptable specimen: Nasal wash*
	Symptomatic ambulatory patient (>6 Days of symptoms)	**Yes** ***Preferred Specimen:*** *Nasopharyngeal, Nasal, Oropharyngeal* *Acceptable specimen: Nasal wash*
	Symptomatic hospitalized patient (>6 days of symptoms)	**Yes** ***Preferred Specimen****: Nasopharyngeal, Nasal, Oropharyngeal,* *Acceptable specimen: Nasal wash* ***Also consider: sputum, tracheal aspirate, BAL***
• Persons **without** symptoms who are prioritized by health departments or clinicians, for any reason, including but not limited to: public health monitoring, sentinel surveillance, or screening of other asymptomatic individuals according to state and local plans	Asymptomatic	Not for routine diagnosis, for surveillance only ***Preferred Specimen:*** *Nasopharyngeal swab* *Acceptable Specimen: Nasal, Oropharyngeal*

See "Instructions for Swab Collection" in Appendix 1 below.

Sensitivity

Sensitivity*, **, *** (%)				
	Days of Illness <8	**Days of Illness ≥8**	**URTI**	**Pneumonia**
Nasopharynx (NP)	95%	64%	92%	60%
Nasal/Anterior Nares (Provider or ObservedSelf-Collection)	93%	UNK	92%	UNK
Oropharynx (OP)	88%	61%	88%	52%
Combination of NP and OP****	98%	76%	96%	72%
Combination of OP and mid-turbinate nasal (MT)****	98%	70%	94%	68%
Sputum	UNK	98%	N/A	99%
BAL/Tracheal Aspirate	UNK	98%	N/A	99%
Saliva	Currently not permited for diagnostic use			

PCR: Polymerase Chain Reaction, URTI: Upper Respiratory Tract Infection, UNK: Unknown, N/A: not applicable
*Sensitivity refers to the proportion of individuals infected with COVID-19 who are found to have a positive test result
**Specificity: 100% (specificity refers to the proportion of individuals not infected with COVID-19 who are found to have a negative test result)

***NP + MT showed similar sensitivity to OP + MT; other sampling sources showed lower sensitivity, including MT alone and saliva (alone or in combination with OP or MT)

****Collection of two samples not recommended due to limited testing supplies. IF the two samples are collected, BOTH swabs should be placed into the same transport media tube

Additional Details

Other Key Features			
	Population Notes	**General Availability**	**FDA Approval**
Nasopharynx (NP)	Any		YES
Nasal/Anterior Nares (Provider or ObservedSelf-Collection)	Symptomatic patients		YES
Oropharynx (OP)	Symptomatic patients		YES
Combination of NP and OP****	Any	Two swabs not recommended	YES
Combination of OP and mid-turbinate nasal (MT)****	Any	Two swabs not recommended	YES
Sputum	Hospitalized patients, later in disease		YES
BAL/Tracheal Aspirate	Hospitalized patients, later in disease		YES
Saliva	TBD		NO

Red flags and concerns:

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Resources/Reference:

- (JAMA) **Interpreting Diagnostic Tests for SARS-CoV-2:** https://jamanetwork.com/journals/jama/fullarticle/2765837

Appendix 1: Instructions for Swab Collection

	Nasopharyngeal	Mid-turbinate	Nasal/Anterior Nares	Oropharyngeal
Who Collects	Healthcare professional	• Healthcare professional Medical-supervised on-site self-collection	• Healthcare professional Medical-supervised on-site self-collection	• Healthcare professional Medical-supervised on-site self-collection
How to Collect	1. Tilt patient's head back 70° 2. Insert flexible shaft mini-tip swab through nares parallel to palate (not upwards) until: a. Resistance is met, OR b. Distance is equivalent to the distance from the patient's ear to their nostril 3. Gently rub and roll swab 4. Leave swab in place for several seconds to absorb secretions 5. Slowly remove swab while rotating it 6. Immediately place swab in sterile tubes containing transport media	1. Tilt patient's head back 70° 2. While gently rotating swab, insert swab about 2.5 cm (≥1 in.) straight back (not up) into nostril until the collar/safety stopping point touches the outside of the nose 3. Rotate swab several times against wall 4. Leave swab in place for several seconds to absorb secretions 5. Repeat for both nostrils using same swab# 6. Immediately place in sterile tube containing transport media	1. Insert swab about 1 cm (0.5 in) inside nares 2. Rotate swab and leave in place for 10- 15 seconds **3. Using same swab, repeat for other nostril** 4. Immediately place in sterile tube containing transport media	1. Insert swab in posterior pharynx and tonsillar areas 2. Rub swab over posterior pharynx and bilateral tonsillar pillars; avoid tongue, teeth, and gums 3. Immediately place swab in sterile tubes containing transport media