SPOTFIRE Sore Throat (ST) Study

NCT06713642

June 20, 2024

PROTOCOL TITLE:

SPOTFIRE ST TITUS STUDY: Provider identified Target populations, Implementation, Test performance, potential Utility, and Satisfaction of SPOTFIRE ST in the Urgent Care

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VERSION NUMBER/DATE:

Protocol Number: BFD-RST-23-010

Protocol Date: June 20, 2024

REVISION HISTORY

Revision #	Version Date	Summary of Changes	Consent Change?

NOTE: Leave this section blank for the initial submission. The revision history should be documented for modifications to approved studies.

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I. PURPOSE

The purpose of this study is to evaluate where urgent care (UC) clinicians see the most benefit for a novel, point of care pharyngitis test, SPOTFIRE ST, and describe its performance, potential clinical utility, and satisfaction of providers and patients with this novel test. The study is separated into three specific aims.

AIM 1. Evaluate which specific patient populations UC providers see the most need and benefit from SPOTFIRE ST, a multiplex point of care pharyngitis test.

AIM 2. Evaluate the performance and effects of test results associated with important clinical outcomes (e.g., prescriptions, additional testing, disposition and follow-up) for patients in the top 3-4 high-risk subpopulations identified by providers in Specific AIM 1.

AIM 3. Evaluate patient and provider satisfaction and future use opportunities of the SPOTFIRE ST Panel testing platform in the clinical pathway for evaluating patients with pharyngitis in UC centers.

II. STUDY DESIGN

AIM 1: Query UC providers prior to SPOTFIRE ST implementation.
UC providers at UW Health will be sent an electronic survey. The survey will aim to understand two important aspects of the current needs/wants of UC providers regarding the evaluation of patients with pharyngitis. First, providers will be asked to rank order patient groups they would most likely want and use a rapid pharyngitis test that would provide bacterial and viral pathogen targets. Second, providers will be asked to rank order aspects or factors that drive them to order a rapid group A strep throat swab for patients presenting to UC with pharyngitis. Additional demographic information about the providers will also be collected.

AIM 2: Implement SPOTFIRE ST Panel into an urgent care setting.
This study will utilize one urgent care facility, from which individual patients will be recruited to participate. The study period will occur during a 3-month period of elevated upper respiratory infection (URI) virus circulation (likely occurring between November 2024 to February 2025) as defined by local surveillance data. Recruitment will be conducted after patients have registered to be seen by Urgent Care providers and while waiting to receive services. Patients presenting with acute pharyngitis and are of the high-risk groups will be eligible to participate.

Some of the high-risk groups are age-based and their eligibility to participate can be determined upon check-in. Other high-risk groups are determined by their

comorbidities and immunocompromising conditions; therefore, study staff may have to screen in the waiting room or wait until the patient is roomed by a nurse or seen by the provider to determine eligibility.

Research staff/coordinators that have been highly trained to run testing on the SPOTFIRE ST and in the proper collection of pharyngeal swabs will be stationed at the urgent care site. Staff will be selected and trained by the Principal Investigator and Biomérieux trainers.
The pharyngeal swab will be tested immediately in the SPOTFIRE ST System by the research coordinator

When finished with the subject, the coordinator will return them to their Urgent Care appointment and deliver the test result upon test completion.

A maximum of 200 patients, representing the top 3-4 patient groups that were identified as benefitting most from a SPOTFIRE ST test through the survey, presenting at the Urgent Care facilities, will be enrolled.

Pharyngeal specimens will be obtained from each subject after informed consent is obtained from each subject or subject's parent(s) or guardian in writing. The study will be conducted in accordance with the Health Insurance Portability and Accountability Act (HIPAA). The patients will receive a token compensation of $25 for their participation.

The patient, parent or guardian will be asked to complete a questionnaire requesting demographic and historical health data.

The patient/clinician will receive results. The clinician will be responsible for recording the result in the medical record as the Research Coordinators will have "view only" access of the medical record.

AIM 3: Query UC providers and patients after SPOTFIRE ST use.
UC providers and patients who utilize SPOTFIRE testing will be sent an electronic or paper survey. The survey will evaluate patient and provider satisfaction with the SPOTFIRE ST testing pathway and evaluate how the platform may be used in the future by UC clinicians.

III. INTERACTIONS WITH SUBJECT DURING PHARYENGEAL SWAB

The Principal Investigator will ensure that the research staff at the UWHealth Urgent Care Centers (UWHUCC) supporting the study adhere to the following steps carefully.

1. This study will be done on an individual basis. Only one patient or parent/guardian and child will participate in the study at a time.
2. After informed consent is completed, the subject will be asked patient

demographic and medical history questions. (Listed in section VI)

3. Study personnel will collect the pharyngeal swab.
4. The subject will be returned to their Urgent Care appointment and their swab will be tested on the SPOTFIRE ST.
5. Study personnel will deliver the test result to the subject and provide a paper post- study survey or schedule the post-study survey to be delivered electronically.
6. Participant comments will be analyzed at least one time during the course of the study. However, more frequent analyses may be necessary, based on the recommendation of the Principal Investigator and/or the clinical coordinator the UWH UCC site.
7. Study personnel will maintain a checklist to ensure that the demographic and medical history questionnaire and survey are completed.
8. One or two face-to-face meetings between the Principal Investigator, his staff, and Biomérieux personnel will likely be required after one month, after two months, and at completion of the study. Study duration will likely be four full months. Additional meetings might be needed face-to-face or by conference call at the request of the Principal Investigator or Biomérieux.

IV. MATERIALS

Materials Provided

The following materials (**Table 1**) will be provided to each site.

Table 1
Provided Materials

Item	Source/Vendor	Number
Spotfire Control System	Biomérieux	1
Spotfire modules	Biomérieux	2
Spotfire r/ST kits	Biomérieux	270
Pharyngeal swabs	Biomérieux	300
Verification and QC materials	Biomérieux	As required

Materials Not Provided

The following materials (**Table 2**) will not be provided by Biomérieux.

Table 2

Materials Not Provided

Item	Source/Vendor	Number
PPE (masks, hand sanitizer, etc.)	Research team will purchase with study funds allocated to supplies	

V. CLINICAL STUDY SUBJECTS

Inclusion Criteria
AIM 1: All UC providers who are credentialled and work at UW Urgent Care center will get a survey.
AIM 2: Any patient with an acute pharyngitis and conforms to one or more of the 3-4 high-risk groups that were identified by UC providers in AIM 1 will be invited to participate when research staff is present. Up to a total of 200 participants.
AIM 3: All UC providers and patients who participated in AIM 2 will receive a post-study survey.

Exclusion Criteria:
AIM 2:
(1) Anatomic anomalies that would prohibit safely collecting a pharyngeal swab specimen
(2) Symptom onset more than 7 days prior to arrival at urgent care
(3) Patient is already on an antiviral medication or an antibiotic medication
(4) Previous participation in the study
(5) Unable to read and understand or refusal to sign the appropriate informed consent/assent forms
(6) Refusal to provide their demographics, household information

VI. PATIENT DEMOGRAPHICS AND MEDICAL HISTORY

Upon patient consent, the attending study personnel will collect basic demographic and medical history information for each enrolled patient. The Principal Investigator will work with the study personnel to ensure that this information is linked to the patient's SPOTFIRE test results.

The following information will be collected but may change slightly prior to publishing the final forms for the study. Should any forms or materials be revised, they will be submitted to Advarra for IRB approval.

Demographics:

- Age
- Sex
- Race
- Ethnicity (Hispanic/non-Hispanic)
- Highest level of education
- Job Title/Occupation

Medical Background:

- Current Symptoms (checklist)
- Severity of Illness
- Days Since Onset of Symptoms
- Measured temperature
- Pregnancy (Y/N)
- Any Chronic Medical Problem (Y/N)
- Tobacco Use (Y/N)
- Routine Prescription Medications (Y/N)
- Influenza Vaccination for current year (Y/N)
- Ever receive a Covid Vaccination? (Y/N)
- Received a Covid Vaccination in the last 12 months? (Y/N)

Post Visit Data (based post-visit on medical chart review)

- Respiratory Infection Diagnosis for this Episode
- Visit test results (Flu, RSV, COVID-19, Rapid strep, strep culture)
- SPOTFIRE ST result
- Flu/Covid vaccine verification
- Antiviral Prescribed
- Antibiotic Prescribed
- Laboratory Testing Ordered (Blood culture, CBC, C-reactive protein, procalcitonin, respiratory virus PCR, urinalysis, urine culture, mono spot, other)
- Imaging Studies
- Chest X-ray
- Disposition
- Visit duration
- 3-week follow up disposition

VII. TEST PROCEDURES

SPOTFIRE ST

The SPOTFIRE ST Analyzers for this study will be used in compliance with the SPOTFIRE ST Analyzer's User Manual. The SPOTFIRE ST will be performed in

accordance with the FDA-cleared package insert instructions for pharyngeal swab specimens. The package insert is attached hereto.

VIII. CLINICAL STUDY LOCATIONS

This study will be conducted at one UW Health Urgent Care Centers (UWHUCC). The Principal Investigator will negotiate with the UWHUCC to determine availability, costs, and use of facilities therein for conduct of the proposed study. The locations of the testing sites are shown in **Table 3**.

Table 3 Study Location

Site Name	Location	Address
UWHUCC West	Madison, WI	7102 Mineral Point Rd, Madison, WI 53717

IX. STUDY DURATION

AIM 1: October – The pre study surveys will be emailed to clinicians. Later this month we will analyze the results to identify target populations for enrollment in AIM 2: November- February - The proposed study will span the influenza season and last approximately four months. Most likely the study will cover the 2024 to 2025 winter upper respiratory infection virus season. The study will likely extend from early November to February 2025. This period is the most common time during which a season's epidemic begins and ends in Wisconsin, but the period of study will be dependent on the evolution of the viral URI season this coming fall and winter.
AIM 3: Participant post-study surveys will be sent out shortly after the UC appointment. Clinician post-study surveys will be sent out after AIM 2 is complete in February.

X. RISKS AND PRECAUTIONS

All specimens obtained from the enrolled subject patients are potentially infectious. Proper care in obtaining and handling of specimens must follow Universal Safety Precautions and standard/institution biohazard procedures for all discarded materials.

All study personnel will have received seasonal influenza and COVID-19 vaccines at least 14 days prior to the start of the study.

XI. DATA ANALYSIS

After the completion of the study, all observations and comments provided by the study personnel and participants will be entered into a master spread sheet/database for analysis.

Possible correlations with patient age, time after onset of illness, underlying demographics and medical history, as well as with user comments regarding swab collection itself will also be analyzed.

XII. ADVERSE EVENTS

All adverse events and complications related to the study procedures must be reported verbally by the Principal Investigator to the Clinical Research Associate at Biomérieux, or its designated representative, within twenty-four (24) hours and in writing within five (5) days of the observation of the adverse event. This information should include the date of onset, a complete description of the event, including severity, duration, action taken and outcome (See Appendix IX- entitled "Adverse Event Report" for further details).

XIII. PRINCIPAL INVESTIGATOR RESPONSIBILITIES

A. Recording of Data

Clinical Study Case Report Forms (CRFs), User Surveys, and Patient Information Sheets will be supplied by Biomérieux. Completed forms will be made available by the Principal Investigator and a copy provided to Biomérieux. The Principal investigator will ensure that the forms are properly generated for each patient enrolled and are legible and maintained securely.

B. Record Retention

Copies of all pertinent study related information will be securely stored and retained by the Principal Investigator for a minimum period of two years following the completion of the study.

C. Confidentiality

The Principal Investigator will be responsible for retaining information about study test results so that Biomérieux or a regulatory agency may access this information, if needed and required by law. All study records provided to Biomérieux will have no subject identification that will link the identification of the subject to the study records. A unique non-identifying study ID number will be used on all study related records without the use of any personal information. All

study records should be retained in a confidential manner for a minimum of two years (or longer, if required by sponsor).

Research records may be inspected and or copied for research or regulatory purposes by Biomérieux or regulatory agencies as required by law. There will be no personal subject identifiers on any copied study data to link subject identity.

Results of this research study may be presented at meetings or in publications; however, there will be no subject identification used and therefore no possibility of disclosure of subject identity will be possible.

D. Subject Consent to Participate

Prior to any procedure being performed, the subject will be informed about the device, and will be given information about the intended purpose, possible benefits, and possible adverse events associated with the study. The procedure and possible hazards to which the subject will be exposed will be explained. An approved informed consent statement will then be read and signed by the subject/parent or legal guardian, and the Principal Investigator or trained designee. The subject/parent or guardian will be provided with a copy of the signed consent to participate statement. Verification of a signed consent to participate statement will be noted on the subject's report forms. The Principal Investigator will provide Biomérieux with an unsigned copy of the consent to participate statement prior to and following approval by his internal Ethics Committee/Institutional Review Board.

E. Ethics Committee/Institutional Review Board

The final approved protocol and the consent to participate statement to be administered must first be approved by a properly constituted Ethics Committee (EC) or Institutional Review Board (IRB). Ethics Committees/Institutional Review Boards in the U.S. must adhere to the Food and Drug Administration Regulations (21 CFR, Part 56). Written approval from the EC/IRB must be forwarded to Biomérieux Corporation before clinical supplies will be shipped.

XIV. ADMINISTRATIVE ASPECTS

A. Modification of the Protocol

Any changes to the protocol that affect study objectives, study design, subject population, study procedures, or significant administrative aspects will require written approval by both parties prior to the implementation of changes. It is the obligation of Biomérieux and the Principal Investigator to determine if a new EC/IRB submission is required prior to the implementation of any amendment to the protocol. If it is required, the amendment cannot be implemented until written approval is obtained from the EC/IRB.

B. Publication of Research Findings

The Principal Investigator is required to provide Biomérieux with complete test results and records for all data developed in this study. Biomérieux is responsible for all submissions to regulatory agencies, e.g. FDA. Biomérieux retains the right to review all publications, including full-length articles, abstracts, posters and presentations, for content prior to submission or delivery. This review is only to ensure accuracy and non-disclosure of information deemed proprietary to Biomérieux and does not deny the investigator the right to publish.

XV REFERENCES