



21120.705 NucliSens easyMAG & (b) (4) Total Nucleic Acid Extraction 21.2

21120.705 NucliSens easyMAG & (b) (4) Total Nucleic Acid Extraction

Copy of version 21.2 (approved and current)

**Last Approval or
Periodic Review Completed** 29-Jun-2020

**Next Periodic Review
Needed On or Before** 29-Jun-2021

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Organization Viracor

Description

Date this test was initially placed in service. 3/28/08.

Comments for version 21.0 (last major revision)

Updated for reduced volume extraction of SARS-CoV-2 on easyMAG & (b) (4) platforms.

Included verbiage for use of Pre Evo automation for pipetting swabs for SARS-CoV-2 extraction.

Comments for version 21.2 (this revision)

Updated Warnings per FDA guidance

Approval and Periodic Review Signatures

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Approval

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Jan-2013 1.0
10:32

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Prior History

Migrating into MediaLab. Format changes and removal of NextDocs numbers.

Replaces LM-Mol-0011 V4.2 added operational procedures related to the use of Post EVO instrument.

Version History

Version	Status	Type	Date Added	Date Effective	Date Retired
21.2	Approved and Current	Minor revision	16-Oct-2020	16-Oct-2020	Indefinite
21.1	Retired	Minor revision	13-Oct-2020	13-Oct-2020	16-Oct-2020
21.0	Retired	Major revision	28-Jun-2020	24-Aug-2020	13-Oct-2020
20.0	Retired	Major revision	11-Mar-2020	13-Mar-2020	24-Aug-2020
19.0	Retired	Major revision	14-May-2019	27-May-2019	13-Mar-2020
18.0	Retired	Major revision	31-Dec-2018	07-Jan-2019	27-May-2019
17.0	Retired	Major revision	10-Oct-2018	29-Oct-2018	07-Jan-2019
16.0	Retired	Major revision	24-Jul-2018	01-Aug-2018	29-Oct-2018
15.0	Retired	Major revision	22-Apr-2018	30-Apr-2018	01-Aug-2018
14.0	Retired	Major revision	08-May-2017	15-May-2017	30-Apr-2018
13.0	Retired	Major revision	14-Mar-2017	03-Apr-2017	15-May-2017
12.0	Retired	Major revision	24-Feb-2017	03-Mar-2017	03-Apr-2017
11.0	Retired	Major revision	13-Feb-2017	20-Feb-2017	03-Mar-2017

10.0	Retired	Major revision	03-Feb-2017	15-Feb-2017	20-Feb-2017
9.0	Retired	Major revision	30-Jan-2017	06-Feb-2017	15-Feb-2017
8.0	Retired	Major revision	10-Aug-2016	15-Aug-2016	06-Feb-2017
7.0	Retired	Major revision	25-Apr-2016	02-May-2016	15-Aug-2016
6.0	Retired	Major revision	20-Apr-2016	Never effective (retired on 26-Apr-2016, before effective date of 02-May-2016)	
5.1	Retired	Minor revision	24-Sep-2015	24-Sep-2015	02-May-2016
5.0	Retired	Major revision	18-Jun-2015	06-Jul-2015	24-Sep-2015
4.1	Retired	Minor revision	24-Oct-2014	01-Nov-2014	06-Jul-2015
4.0	Retired	Major revision	17-Oct-2014	Never effective (retired on 28-Oct-2014, before effective date of 01-Nov-2014)	
3.1	Retired	Minor revision	01-Jul-2014	01-Jul-2014	24-Oct-2014
3.0	Retired	Major revision	22-Jan-2014	30-May-2014	01-Jul-2014
2.0	Retired	Major revision	20-Nov-2013	27-Nov-2013	30-May-2014
1.1	Retired	Minor revision	15-Jan-2013	15-Jan-2013	27-Nov-2013
1.0	Retired	Initial version	30-Nov-2012	15-Jan-2013	15-Jan-2013

Linked Documents

- 21120.615 easyMAG Manual Run Map
- 21120.2580 easyMAG Job Aids
- 21120.2866 easyMAG Training Checklist

NucliSENS easyMAG and (b) (4) Total Nucleic Acid Extraction

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INTENDED USE

The NucliSENS easyMAG and (b) (4) platforms are intended for the automated isolation (purification and concentration) of total nucleic acids (DNA and RNA) from biological specimens. The NucliSENS easyMAG and (b) (4) are both *in vitro* diagnostic medical devices.

TEST INFORMATION

This SOP applies to nucleic acid extraction of specimens designated for easyMAG and (b) (4) extraction platforms as indicated in *Specimen Processing Guide* or as otherwise directed by laboratory management.

METHOD PRINCIPLE

The NucliSENS system is based on a generic method for binding nucleic acids from complex biological specimens to Magnetic Silica. The system works with a liquid specimen. A specimen is mixed with a lysis buffer containing a chaotropic agent (GuSCN). Any cellular matter, viral particles, bacteria, or fungi present in the specimen will be disrupted (lysed) in the presence of the chaotropic, thereby releasing the nucleic acids. The lysis buffer inactivates any nucleases present in the specimen. The isolation process is initiated by adding Magnetic Silica to the lysed specimen. Nucleic acids present in the lysates will bind to the Magnetic Silica under the high salt conditions.

The Magnetic Silica are then washed several times using 2 wash buffers. The nucleic acids are then released (eluted) from the Magnetic Silica and concentrated in a specified volume of the elution buffer. This elution process is accelerated by flushing the Magnetic Silica in the elution buffer at an elevated temperature. Finally, the Magnetic Silica is separated from the elution buffer before the concentrated nucleic acid solution is available for detection in a downstream application.

The NucliSENS system supports two workflow scenarios. The first scenario, called the on board workflow, adds the lysis buffer to the specimens strips while they are loaded on the instrument. The instrument adds the lysis buffer to the specimens and controls the timing for the lysis step. With the second scenario, called the off board workflow, the lysis step is performed manually in the sample strips prior to loading on the instrument. After sample lysis, the sample strips are loaded on the instrument. With both scenarios, under high salt conditions, nucleic acid will bind to the magnetic silica particles. The silica particles act as solid phase and non-nucleic acid components are removed by several washing steps in the instrument. Next, nucleic acids are eluted from the silica particles and the silica particles are removed from the extracted specimens by the NucliSENS instrument. The resulting eluate contains purified and concentrated total nucleic acids.

SPECIMEN REQUIREMENTS

Patient Preparation

None

Specimen Type and Handling

Refer to the *Specimen Processing Guide* for acceptable assays, specimen types, volume requirements, comments and reject conditions.

REAGENTS AND MATERIALS

NucliSENS® easyMAG® reagents have been validated for use on both NucliSENS easyMAG and (b) (4) instruments Description	Source	Part/Cat No	Storage	Expiration
(b) (4)				
Phosphate Buffered Saline (PBS)	(b) (4)			
Molecular grade H ₂ O	(b) (4)			

Reagent Handling

Any new box or bottle of reagent opened by any CLS must be checked against the current list of reagent name, lot number and expiry dates to ensure the current lot remains in use and expired reagents are discarded.

Expiry dates shown on the NucliSENS component labels indicate the date beyond which the reagents or disposables should no longer be used. The barcode labels on the reagents and disposables contain information on the expiry date which is interpreted by the software. The software will alert the user when an expired reagent (based on the manufacturer’s label) or disposable is detected. Store reagents at temperature conditions listed above when not in use.

(b) (4) may have a slight to appreciable yellowish color. This coloration is normal and will not have any effect on the performance of the reagents. Storage of (b) (4) may give rise to the appearance of crystals due to the high salt concentration. These crystals have to be dissolved during reagent preparation.

Once loaded in the reagent area of the NucliSENS easyMAG or (b) (4) instrument, the (b) (4) (b) (4) Buffers should be stored on board the instrument. When the extraction buffers are disconnected and reconnected, there is a high risk of bacterial contamination.

The (b) (4) after opening. The software will not alert for the expiration date applied upon opening and loading the reagent onto the system.

Combining NucliSENS Reagents

This procedure applies to the following (b) (4)

Combining NucliSENS reagents will be performed by Lab Management and other trained CLS as assigned.

Each individual reagent's expiration date will be located on the (b) (4) label. The expiration date for the above reagents is one month after its individual Date Opened date or the manufacturer's expiration date, whichever occurs first.

Note: The last bottle of the current lot or reagent that is within three days of expiration are ineligible for combining and must be fully consumed or replaced with a new reagent bottle.

1. Using clean gloves remove the bottle cap or connector/suction tube (if reagent is on the instrument) from the reagent bottle with the earliest labeled expiration date. Clean the bottle connector with Kim Wipe tissue and molecular grade water. To reduce the risk of contamination, do not allow the suction tube to contact any surfaces or potential contaminants. If the bottle connector/suction tube must be set down, place on clean paper towels.
2. Verify the reagent name on both bottles match.
3. Verify the reagent lot numbers on both bottles match.
4. Verify neither bottle is within three days of its expiration date. The reagent's expiration date is labeled on the bottle and is one month after its individual Date Opened date or the manufacturer's expiration date, whichever occurs first.
5. Compare the two reagent bottles and top off the reagent bottle with the earliest labeled expiration date.
6. Top off the reagent bottle with the earliest labeled expiration date. Always pour the bottle with the later expiration date into the bottle with the earliest labeled expiration date.
 - a. Do not overfill bottles.
 - b. Do not fill bottle so the reagent goes up to the neck of the bottle.
 - c. Do not add reagent to a newly opened bottle.
7. Re-cap with bottle with cap or connector/suction tube.
8. Ensure the topped off bottle is placed on a heavy-use instrument so that reagents are consumed regularly. Place newly opened bottles on systems that receive lighter use.
9. Verify when reagent bottle is topped off, loaded and scanned into the instrument, that the new volume is correctly displayed on the reagent on-screen display.
10. Mark empty reagent bottle with an X using a permanent marker. Rinse empty bottles with tap water and discard in recycle bins.

CALIBRATORS AND STANDARDS

Refer to 21120.369 *Analytical Quality Control: Assay Calibration and Calibration Verification* for instructions and guidelines for maintaining the analytical accuracy of laboratory test methods through regular calibration and calibration verification procedures.

The quality control program for this test is established in accordance with 21120.369 *Analytical Quality Control: Assay Calibration and Calibration Verification*.

Description	Source	Part/Cat No	Storage
<div>(b) (4)</div>			

Internal Control preparation

(b) (4)

is performed through evaluation of internal control in downstream testing.

(b) (4)

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(b) (4)

Control Procedure

(b) (4)
For quantitative assays, both levels of controls for the assay
will be extracted and analyzed (b) (4)

(b) (4)

Establishing QC Control range for new control lot number

(b) (4)

(b) (4)

Prior to use for this procedure, a (b) (4) is submitted for extraction with each
qPCR extraction run.

Quality control Acceptance Criteria/Repeat Criteria

Refer to 21120.578 *PCR and RT PCR Acceptance and Retest Criteria* for acceptance criteria and corrective actions for
(b) (4)

PROFICIENCY TESTING

Tests associated with this procedure shall be challenged by in-house and external proficiency testing (b) (4)
(b) (4)

EQUIPMENT AND SUPPLIES

Description	
(b) (4)	(b) (4) easyMAG instrument with barcode scanner
(b) (4)	instrument with barcode scanner
(b) (4)	(Electronic multichannel pipette) programmed for use with NucliSENS easyMAG instrument
NucliSENS easyMAG Cartridges	
NucliSENS easyMAG Syringes	
NucliSENS easyMAG Cartridge carriers and plastic tubs	
1.5 mL or 2 mL tubes	
(b) (4)	reservoir: 30 mL
Pipette tips with aerosol barrier: 10 µL, 200 µL, 300 µL and 1000 µL sizes	
Pipettes to accommodate above listed tip sizes	
DNase and RNase free 96-well plates for nucleic acid removal and storage on high throughput runs	
Refrigerator	(b) (4)
Freezer	(b) (4)
Sterile polystyrene reservoir(s)	

Handling of Consumables

All consumables must be handled with clean gloves.

PCR testing process requires specific handling of consumables to prevent potential contamination. NucliSENS cartridges must be removed from its packing container using clean gloves. The white cover must remain in place to protect the syringes from dust and other contaminants. Note: The white cover is not recyclable.

DNase and RNase free 96-well plates must not be taken out of the packaging until immediately prior to use. Other consumables must be covered when not in use to prevent potential contamination (tips, reagent reservoirs, etc.).

Preventative Maintenance

Follow maintenance procedures for equipment as indicated in 21120.812 *Operation, Qualification and Maintenance of the NucliSENS easyMAG* and 21120.6763 *Operation Qualification and Maintenance of the NucliSENS* (b) (4)

Environmental Conditions

Temperature: (b) (4)

Humidity: (b) (4)

Power Supply

PROCEDURE

easyMAG Startup

(b) (4)

(b) (4) **Startup**

Reagent Preparation

21

(b) (4)

Preparation of (b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Positive Identification checks for manual pipetting of samples into the sample vessel (cartridge)

(b) (4)

Programming easyMAG for Off Board Lysis

(b) (4)

(b) (4)

Programming easyMAG for On Board Lysis

Manual Maps

13

(b) (4)

(b) (4)

Starting a NucliSENS easyMAG Extraction Run

(b) (4)

FDA-CBER-2022-1614-4806224

(b) (4)

On Board Lysis on the easyMAG instrument

(b) (4)

Loading Sample Vessels (cartridges) and Aspirator Disposables on the (b) (4) Instrument

(b) (4)

(b) (4)

(b) (4)



(b) (4)

Off-board Lysis with the (b) (4) Instrument

(b) (4)

(b) (4)

(b) (4) system or instrument errors

(b) (4)

(b) (4)

(b) (4)

(b) (4)

End of Run on (b) (4)

(b) (4)

(b) (4)

(b) (4)

(b) (4)

Quality Assurance

(b) (4)

CALCULATIONS

Refer to Related Documents section

RESULT REPORTING AND REPEAT CRITERIA

Refer to Related Documents section

EXPECTED VALUES AND REFERENCE RANGES

Refer to Related Documents section

CLINICAL SIGNIFICANCE

N/A

PROCEDURE NOTES

Documenting Errors

All anomalies, errors, deviations, and exceptions must be documented on the run map. For those which require management approval, the person approving must notate their approval and any justification and further comments required, followed by their initials and the date of the approval.

Testing System Unavailable

Viracor Laboratories takes precautions to ensure that testing systems do not have prolonged outages by ensuring that redundant equipment is available for all testing platforms. Therefore, the backup plan for a system outage is always to run patient specimens on the redundant system for the impacted assay(s). In rare instances, both the primary and secondary platforms can be out of service. In these cases, specimens are stored according to their individual storage

requirements until such time as the testing system is back to operational status and testing may resume again. In extreme cases whereby an entire testing system will be completely down for (b) (4), clients will be notified and alternative testing options, potentially at other facilities, will be communicated to them where possible and at their discretion.

LIMITATIONS OF THE METHOD

N/A

PERFORMANCE SPECIFICATIONS

N/A

WARNINGS

- The Viracor SARS-CoV-2 assay has not been FDA cleared or approved;
- The Viracor SARS-CoV-2 assay has been authorized by FDA under an EUA for use by the authorized laboratory: Viracor Eurofins Clinical Diagnostics Laboratory located at 1001 NW Technology Dr., Lee's Summit, MO, certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, and meet the requirements to perform high complexity tests;
- The Viracor SARS-CoV-2 assay has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and
- The Viracor SARS-CoV-2 assay is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

SAFETY

The following personal protective equipment will be applied as directed in currently effective Safety SOPs, including but not limited to, gloves, masks, lab coats, face shields and eye protection.

Personnel executing these procedures must be trained on effective Safety SOPs as listed in 21120.265 *Safety Program*.

See Material Safety Data Sheet (MSDS) manual for further details regarding all agents in the kit.

RELATED DOCUMENTS

21120.265 *Safety Program*

21120.369 *Analytical Quality Control: Assay Calibration and Calibration Verification*

21120.554 *Real-time PCR and RT-PCR Results Calculation and Rounding*

21120.578 *PCR and RT PCR Acceptance and Retest Criteria*

21120.580 (b) (4) *User Procedures*

21120.595 *Specimen Processing Guide*

21120.596 *Clinical Laboratory Processing Guide*

21120.600 *Pre-processing Procedures for ID tests and Pre-processing Temperature Requirements for ID and AI*

21120.615 *easyMAG Manual Run Map*

21120.716 *Acceptance and Retest Criteria for PCR and RT-PCR Assays*

21120.812 *Operation, Qualification and Maintenance of the NucliSENS easyMAG*
21120.813 *easyMAG Monthly PM Log*
21120.2580 *easyMAG Job Aids*
21120.3153 *easyMAG Lysis Buffer and Magnetic Silica Reagent Log*
21120.6763 *Operation Qualification and Maintenance of the (b) (4)*
21120.6764 (b) (4) *Maintenance Log*
21120.6943 (b) (4) *Job Aid*
21120.6954 (b) (4) *Tip Count Job Aid*
21120.7082 *Operation of (b) (4) Service Process for qPCR Workflows*
21120.7151 *easyMAG & (b) (4) Job Aid - NucliSENS Extraction Chart*

REFERENCES

NucliSENS easyMAG User Manual v 2.0, Ref. 280163, July 2007

(b) (4)

ATTACHMENTS

N/A