Example of a ChannelCheck™ Policy for Detection of Residual Organic Soils Inside Various Channels of lumened items and/or residual soils from endoscopic valves/caps.

NOTE: This document is an example policy that may be instituted in a healthcare facility for the detection of residual organic soils inside various channels. The actual policy in a facility must be based on variables, logistics, and risk-assessments specific to your facility.

Subject: Detection of residual organic soils inside various channels of lumened items and/or residual soils from endoscopic valves/caps.

Department: Central Service/Endoscopy

Approved By: [Name of Dept Supervisor/Manager]

Effective: [Enter date when this will take effect]

Revised: August 2021

Purpose: For detection of specific residual organic soils inside lumened items and/or from endoscopic valves/caps, to help ensure proper cleaning, and reduce risk to patients.

Policy: The ChannelCheck™ tests for three common organic soils at once: blood, protein, and carbohydrates. Random testing of various instruments with lumens is to be performed as stated in the device manufacturer's guidelines to ensure the cleaning process is being conducted properly.

Rationale: According AAMI ST91, healthcare facilities should form a comprehensive quality assurance and safety program to monitor all aspects of endoscope processing. This program should incorporate both visual inspections and testing of the equipment to find conditions that may affect the cleaning or disinfecting processes.

Standards and Professional Society Recommendations:

1. **ANSI/AAMI ST91:2015, Flexible and semi-rigid endoscope processing in health care facilities**

    a. "Visual inspection alone may not be sufficient for assessing the efficacy of cleaning processes; the use of methods that are able to measure organic residues that are not detectable using visual inspection should be considered in facility cleaning policy and procedures."
    b. "When developing a user verification procedure for the cleaning process, reprocessing personnel should ensure that:

i. The endoscope manufacturer has completed validation of the recommended cleaning process and provided a written IFU detailing the process.
ii. The facility has established, clarified, and documented a standard cleaning process for the device.
iii. Facilities should develop a defined program of cleaning verification that includes frequency of testing, number, and types of endoscopes to be tested.
iv. Cleaning verification results are documented.
v. The facility has established, clarified, and documented a process to address cleaning verification failures.
vi. The facility has established an education, training, and competency assessment program that verifies personnel are consistently achieving the expected level of cleaning."

c. "Cleaning verification of flexible and semi-rigid endoscopes by users should include…Visual inspection combined with other verification methods… that allow the assessment of both external surfaces and internal housing and channels."
d. "Residual organic soil and microbial contamination may be present on an accessible surface even though the device looks clean" (Visrodia et al. 2014).
e. "The use of methods that are able to quantitatively or chemically detect organic residues that are not detectable using visual inspection should be considered and included in facility policies and procedures on device cleaning."
f. "Several technologies are available that can be used to measure the levels of organic soil and microbial contamination on the cleaned device. The published studies that have evaluated the specific markers that can be used to determine cleaning efficacy have indicated that the following markers are useful for benchmarking purposes by the user. They include protein, carbohydrate, hemoglobin (blood), adenosine triphosphate (ATP) and an enzyme that detects specific bacteria" (Alfa 2012, Alfa 2013, Alfa 2014, Visrodia 2014).
g. "Manufacturer's written IFU should be consulted for recommendations of types and frequency of cleaning efficacy testing."
h. "The frequency of testing the efficacy of the manual cleaning step should occur on a regular basis, weekly or preferably daily" (Drosnock 2014, Alfa 2014).

2. AORN Guideline for Processing Flexible Endoscopes 2016:

a. "Manual cleaning of flexible endoscopes should be verified using cleaning verification tests when new endoscopes are purchased and at established intervals (e.g., after each use daily)."

i. "Cleaning verification tests are used to verify the ability of the cleaning process to remove, or reduce to an acceptable level, the organic soil and microbial contamination that occurs during use of a reusable device. Cleaning verification tests include…chemical reagent tests for detecting clinically relevant soils (e.g., protein, carbohydrate). Periodic verification of cleaning effectiveness may help reduce errors in manual cleaning and improve effectiveness."

ii. "Auditing the manual cleaning of flexible endoscopes provides an objective method for verifying cleanliness and helps ensure that insufficiently cleaned flexible endoscopes are recleaned before HLD or sterilization."

iii. "There are a number of tests that can be used to assess cleaning efficacy. Chemical tests involve the use of a reagent and observing for a color change that indicates the presence of organic markers such as protein or blood. In a dual phase (i.e., simulated-use, in-use) study to validate the use of an audit tool composed of reagent test strips in 43 endoscopy clinics across Canada, Alfa et al collected samples from 30 patient-used endoscopes (i.e., 10 colonoscopes, 10 duodenoscopes, 10 gastroscopes) and tested them for residual protein, carbohydrate, and hemoglobin using the audit tool test strips. The test strips had three reagent pads designed to rapidly detect organic residuals of protein, carbohydrate, and hemoglobin after manual cleaning. The researchers confirmed that the audit tool flagged endoscopes with residual protein, hemoglobin, or carbohydrate."

v. "There are quantitative tests that can be used for cleaning verification testing of other residual soils, including protein, carbohydrate, and hemoglobin."

vi. "The multidisciplinary team should evaluate the need to implement protocols for cleaning verification testing of flexible duodenoscopes with elevator channels."

b. "Records related to flexible endoscope processing should include the date and time, identity of the endoscope and endoscope accessories, method and verification of cleaning and results of cleaning verification testing. . .."

3. SGNA Standard of Infection Prevention in the Gastroenterology Setting:

a. "'Visibly clean' is a method routinely used to assess the adequacy of manual cleaning (AAMI, 2015; Rutala & Weber, 2008). This may involve the use of a magnifying glass to inspect for gross soil. Visual inspection is insufficient to determine cleaning adequacy in narrow and internal channels of a scope and cannot detect microorganisms or bioburden (Alfa, Olson, & Murray, 2014). … Rapid cleaning verification tools are available. These tools can provide documentation on cleaning efficacy but do not reflect microbial activity." Real-time "testing of endoscope lumen or elevator channel should be done immediately after manual cleaning so that any improperly cleaned devices are recleaned prior to HLD … Facilities should consider the regular use of these processes to verify ongoing cleaning adequacy (Alfa, 2013) and to assess reprocessing efficacy" (USFDA, 2018a, 2018b).

b. "Once there is confirmation that an endoscope has been properly reprocessed, it is suggested that a system exist for identifying scopes that are clean and ready to use" (Rutala & Weber, 2016c; CDC, 2017a).

4. SGNA Standards of Infection Prevention in Reprocessing Flexible Gastrointestinal Endoscopes:

a. "It is a challenge to visualize internal channels … Literature suggests that, to confirm the adequacy of manual cleaning, a rapid cleaning monitor (or rapid audit tool) for residual organic soil can be used prior to HLD" (Visrodia et al., 2014). (Visrodia et al., 2014; Petersen et al., 2017). "If the tool results are positive, this allows for the re-cleaning of the endoscope prior to disinfection. The frequency of the testing should be determined by the individual institutions" (Alfa, Fatima, & Olson, 2013; Alfa, Olson, & Murray, 2014; AAMI, 2015; ASGE, 2014).

5. ANSI/AAMI ST79 and Quality Monitoring:

a. "Cleaning efficacy tests that are performed following reprocessing are used to verify the ability of a cleaning process to remove or reduce to an acceptable level the organic soil and microbial contamination that occurs during the use of reusable devices."
b. "However, residual organic soil and microbial contamination could be present on an accessible surface even though the device "looks clean."
c. "Furthermore, direct visual inspection is not possible for the inner components of medical devices that have lumens or that are of non-sealed tubular construction (e.g., flexible endoscope channels, laparoscopic accessory devices, biopsy forceps)."
d. "Ideally, cleaning verification by users should include…visual inspection combined with other verification methods that allow the assessment of both external surfaces and the inner housing and channels of medical devices. . .."

6. ASGE: Technologies for monitoring the quality of endoscope reprocessing, 2014:

a. "Bioburden assays: Currently available methods allow rapid evaluation of residual bioburden and organic matter from the endoscope channels (e.g., ChannelCheck™; Healthmark Industries Co., Fraser, MI) … ChannelCheck™ is able to detect protein, blood and carbohydrate residues within the biopsy channel of endoscopes."

b. "Methodology. All the above tests are easily and rapidly performed … The ChannelCheck™ test offers the advantages of ease of test sample collection, simple test method using a test strip similar to a urine dipstick, as well as detection of a wider range of biological soils. The assay uses test strips with 3 pads that allow detection of residual carbohydrate, protein, and hemoglobin. The endoscope's biopsy channel is flushed with 10 mL of pre-packaged chlorine-free water, followed by 10 mL of air to promote expulsion of the water from the distal end of the endoscope. This water is collected into a sample collection container, and the test strip is immersed within it for 5 seconds. The 3 test pads on the test strip indicate the presence of residual carbohydrate, protein, and hemoglobin by a

color change within 90 seconds. The colors on the test strip are compared with those on a color indicator chart provided on the test strip bottle."

c. "Potential Clinical Applications: Minimizing the potential for transmission of pathogens by using flexible endoscopes is an important issue for facilities at which endoscopy is performed. These technologies offer endoscopy units the ability to implement surveillance strategies, which may potentially improve the quality of endoscope reprocessing."

d. "Emerging technologies for monitoring the quality of endoscope reprocessing offer the ability to perform rapid surveillance, which may potentially help reinforce adherence to the many steps in reprocessing."

7. **Ofstead & Associates,** Inc. SGNA Poster presentation 2015. "The effectiveness of reprocessing in accordance with current guidelines: Viable microbes and organic residue found on patient-ready colonoscopes and gastroscopes."
   a. Recommendations: Ensure reprocessing practices meet or exceed standards.
   b. Use rapid indicators to monitor cleaning effectiveness.

8. **FDA, CDC, VA Joint Safety Communication**

   a. "Establish an institutional program for endoscope processing along with written procedures for monitoring adherence to the program and a chain of accountability."
   b. "Ensure that those responsible for endoscope processing understand the importance of this job and that they maintain proficiency in performing it for each type of endoscope they handle."
   c. "Train employees to set up, clean, disinfect or sterilize, and store endoscopy equipment properly. Periodically retrain and assess competence."

9. **CDC, Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008:**

   a. Clusters of infections "… highlight the importance of training, proper model-specific endoscope connector systems, and quality-control procedures to ensure compliance with endoscope manufacturer recommendations and professional organization guidelines."
   b. "To achieve and maintain competency, train each member of the staff that reprocesses semi-critical and/or critical instruments as follows: 1) provide hands-on training according to the institutional policy for reprocessing critical and semi-critical devices; 2) supervise all work until competency is documented for each reprocessing task; 3) conduct competency testing at beginning of employment and regularly thereafter (e.g., annually)"; and
   c. "Conduct infection control rounds periodically (e.g., annually) in high-risk reprocessing areas (e.g., the Gastroenterology Clinic, Central Processing); ensure reprocessing instructions are current and accurate and are correctly implemented."

10. CDC, Interim Protocol for Healthcare Facilities Regarding Surveillance for Bacterial Contamination of Duodenoscopes after Reprocessing, 2015

a. "Non-culture methods have been used to assess duodenoscope reprocessing by detecting residual organic material after cleaning. While individual facilities might choose to use such non-culture assays, more work is needed to interpret their results since non-culture methods lack consistent correlation to bacterial concentrations. They might, however, provide insight regarding the quality of duodenoscope reprocessing if systematically validated."

b. "Non-culture methods are indicators of the presence of residual organic material after cleaning such as: protein, carbohydrate, and hemoglobin. These include: EndoCheck™, ChannelCheck™, ProCheck™, HemoCheck™, and FlexiCheck™. ATP is another marker that can be used to indicate the presence of residual patient material."

ChannelCheck™ Information:

The ChannelCheck™ is designed to allow in-house testing of any cleaned channel/lumened item (instrument) and allows facilities to verify that adequate cleaning has been achieved.

ChannelCheck™ is the first product capable of testing for residual organic soils inside the various channels/lumens (such as a flexible endoscopes & suction tubes) no matter the channel/lumen size. ChannelCheck™ tests for three common organic soils at once: blood, protein, and carbohydrates.

As noted, channelled/lumened items (instruments) provide a difficult challenge, whether it is a suction tube or a flexible endoscope. A quality improvement system that allows you to monitor the inside of any channel/lumen is an important function of any Infection Control program. Testing channels/lumen instruments with the ChannelCheck™ and recording results in a log is one such system.

The use of the ChannelCheck™ is an excellent tool to use for training of new employees as well as establishing a Quality Improvement Program for checking whether manual or automatic cleaning of these items is done properly. The frequency of testing the various channel/lumen instruments (including flexible endoscopes) should be based on institutional policy that references current standards and guidelines.

Lot Control (*Control Test)*:

The first step when opening a new bottle of ChannelCheck™ residual soil test strips is to check the performance of the lot with the included vial of control soil. This will ensure the reagent in each of the test pads has remained active after shipment. This is only done once per bottle and only two control vials (one per bottle) are included. The test vial holds enough lyophilized test soil to create a single milliliter of test soil. To test:

1. *Remove and Re-hydrate Soil*. Remove the vial of dehydrated test soil from the box. To re-hydrate the soil, unscrew the cap from the vial, then add exactly 1 mL of pre-packaged chlorine-free water to the vial. Screw the cap back on the vial, being sure you have a tight seal.
2. *Shake Vigorously*. Shake the vial vigorously for at least one-minute. Check the vial to make sure the soil has been completely re-hydrated.
3. *Retrieve a Single Test Strip*. Retrieve a single ChannelCheck™ test strip from the pack.
4. *Dip the test into the vial for 5 seconds*. Make sure to completely immerse all 3 test pads into the solution.
5. *Dab Side of Test Strip Absorbent Pad*. After 5 seconds, remove the test strip and dab the side of the moistened test pad on a clean, dry absorbent pad, to wick off excess water.
6. *Wait 5 minutes*. The reagents in the test pads require time to interact with the residual soil. Wait a complete 5 minutes before reading the results.
7. *Compare Results to Control Color Chart*. After 5 minutes, compare the results to the Control Color Chart. The colors of each test pad should closely approximate the colors found on the Control Color Chart.
8. *Record Results*. On a log sheet, record the results of each pad.

Procedure:

After the cleaning process is complete is when you will test the channel /lumen item. This is done before sterilization or High-Level Disinfection.

Lumened Item Procedure:

1. Use a syringe with exactly 10 mL of pre-packaged chlorine-free water.
2. Place the distal end of the lumen inside a clean collection container (e.g., sterile specimen container or supplied zipper bag).
3. Inject the 10 mL of pre-packaged chlorine-free water through the proximal part of the lumen/channel followed by 10 mL of air to aid in complete flushing of the fluid. Collect all the sample fluid that drains from the distal end into the clean container.
4. *Dip test strip into sample water*. Dip the test strip into the recaptured water ensuring that all 3 pads are completely immersed. Keep test strip immersed for 5 seconds.
5. Remove the test strip.
6. Dab the side of the test strip on an absorbent surface (e.g., paper towel) to absorb excess moisture.

7. Compare the test strip's colors (*after 90 seconds*) to the Control Color Chart.
8. Record the results for all 3 pads.

Should any of the pads show there is residual soil, re-clean the device (according to facility policy) and then retest. Record your results in a log.

Once all three pads test negative, continue to the next step in your facilities process.

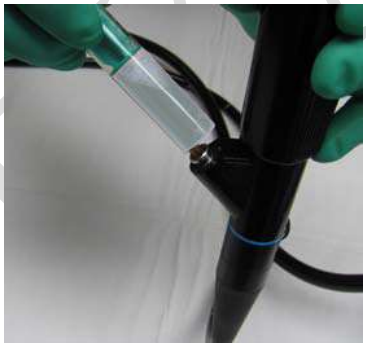
Flexible Endoscope Testing Procedure:

After the manual cleaning process is complete is when you will test the flexible endoscope with ChannelCheck™. This is performed before High Level Disinfection or sterilization.

1. Use a syringe with exactly 10 mL of pre-packaged chlorine-free water.
2. Inject that water through the biopsy/suction channel followed by 10 mL of air to aid in complete flushing of the fluid. Collect all the fluid that drains from the distal end in a clean sample container.
3. Dip the test strip into the recaptured water, ensuring that all three pads are completely immersed. Keep test strip immersed for 5 seconds.
4. Remove the test strip.
5. Dab the side of the test strip on an absorbent surface (e.g., paper towel) to absorb excess moisture.
6. Compare the test strip's colors (*after 90 seconds*) to the Control Color Chart.
7. Record the results for all 3 pads.

Should any of the pads indicate there is residual soil, re-clean the device (according to facility policy) and then retest. Record your results in a log. Once all three pads are negative proceed to the next step in your facility's process.

All test results must be documented



Flush a flexible endoscope channel

Capture and test the solution

Flexible Endoscope Valve and Biopsy Cap Testing Procedure:

Test the endoscope valves/caps with ChannelCheck™ after the manual cleaning process is complete. This is performed before high-level disinfection/sterilization.

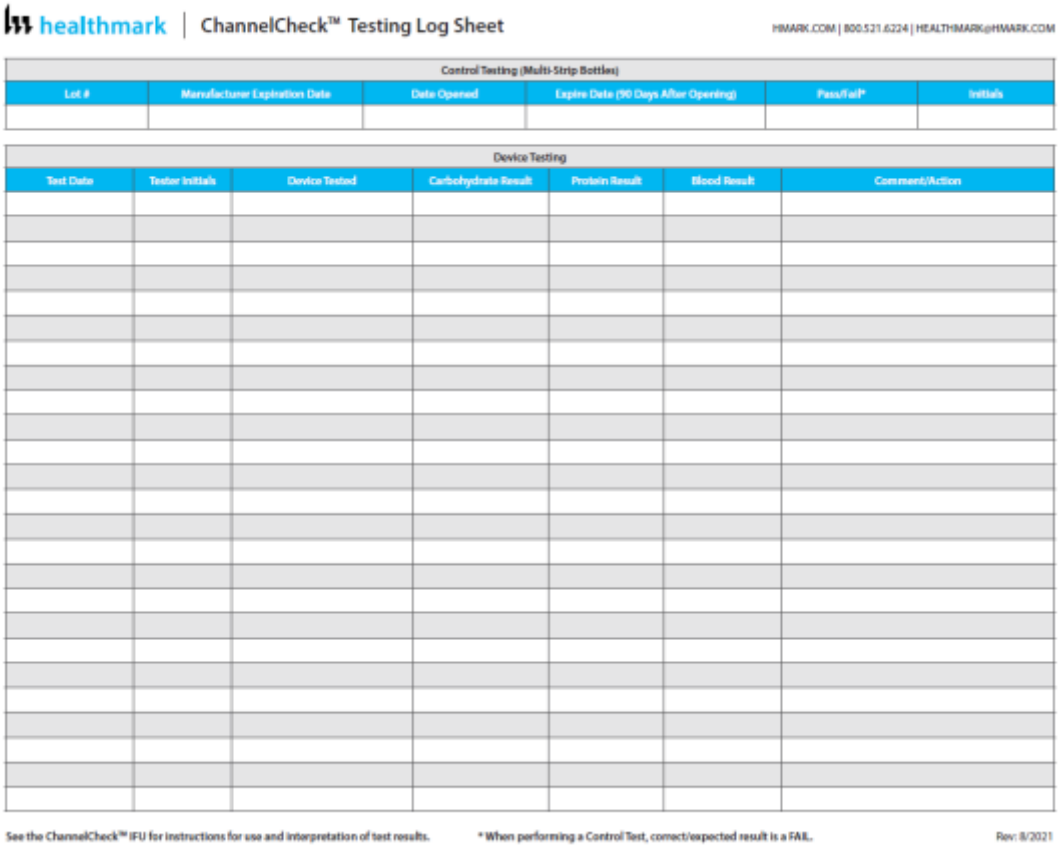
1. Place valves/caps to be tested into a sterile specimen cup or equivalent with a lid. (Note**:** Separate cups should be used for each valve or cap).
2. Add 10 mL of pre-packaged chlorine-free water.
3. Close the sterile specimen cup.
4. Shake the specimen cup to mix well and to remove any potential soil.
5. Remove a test strip from the ChannelCheck™ bottle and dip into the water in the specimen cup.
6. Dip the test strip into the recaptured water ensuring that all three pads are completely immersed. Keep test strip immersed for 5 seconds.
7. Remove the test strip.
8. Dab the side of the test strip on an absorbent surface (e.g., paper towel) to absorb excess moisture.
9. Compare the test strip's colors (*after 90 seconds*) to the Control Color Chart.
10. Record the results for all 3 pads.
11. Dry valves/caps in accordance with the manufacturer's IFU and continue to high-level disinfection or sterilization.

Should any of the pads indicate there is residual soil, re-clean the valves/caps (according to facility policy) and then retest. Record your results in a log. Once all three pads are negative proceed to the next step in your facility's process. All test results must be documented.

Example Valves to be tested

Valve in Cup

ChannelCheck™ Testing Log Sheet:



healthmark | ChannelCheck™ Testing Log Sheet

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Control Testing (Multi-Strip Bottles)					
Lot #	Manufacturer Expiration Date	Date Opened	Expire Date (90 Days After Opening)	Pass/Fail*	Initials

Device Testing						
Test Date	Tester Initials	Device Tested	Carbohydrate Result	Protein Result	Blood Result	Comment/Action

See the ChannelCheck™ IFU for instructions for use and interpretation of test results. * When performing a Control Test, correct/expected result is a FAIL. Rev: 8/2021

*If a flexible endoscope is tested make sure you document the serial number.

Note: Read Product Insert before use. Do not touch the test area of any strip. Store strip at temperatures between 59ºF and 86ºF (15º-30ºC). Do not remove desiccant from bottle. Remove only enough strips for immediate use. Replace cap promptly and tightly. Testing reading time is 90 seconds and record results at once. Compare results to provided Color Control Chart. Record results as a (N) negative result, no residual; or as (P) positive for residual.

Comments:

Sample Competency for Using the ChannelCheck™:

Name:

Competency Statement: Complies with policy and procedure for cleaning and testing endoscopes (biopsy channels) using the ChannelCheck™.

Key
1 = Performs independently and consistently. Request assistance in new situations.
2 = Performs with minimal guidance and direction. Request assistance when necessary.
3 = Performs with maximal guidance and direction. Preceptor dependent. Consistently needs assistance.

Comments:
_____
_____
_____

Competency Achieved: _____ Date: _____

Evaluator: _____

Learner: _____

Critical Behavior	1	2	3
CONTROL TEST			
Reviews ChannelCheck™ IFU related to performing Control Test.			
Verbalizes when to complete Control Test.			
Removes vial of dehydrated test soil from the box and rehydrates soil.			
Unscrews cap from the vial, adds exactly 1 mL of pre-packaged chlorine-free water to the vial, screws cap back on the vial ensuring a tight seal.			
Shakes vial vigorously for at least one minute. Checks vial to make sure the soil has been completely rehydrated.			
Retrieves single test strip from test strip container.			
Dips test strip into vial for 5 seconds, making sure to completely immerse all three test pads into the solution. Removes test strip and dabs side of test strip on absorbent pad.			
Uses timer and waits full 5 minutes.			
At 5 minutes, compares pads on test strip to Control Color Chart.			
Records results for each pad on established log sheet.			
CLINICAL USE OF CHANNELCHECK™			
Reviews institutional policy/protocol re: cleaning verification testing.			
Reviews ChannelCheck™ IFU related to performing clinical test.			
Sets up testing supplies on clean surface: syringe, pre-packaged chlorine-free water, test strip, sample collection bag (e.g., supplied Ziplock bag), Control Color Chart, timer.			

Fills new syringe with 10 mL pre-packaged chlorine-free water.			
Without reaching into sample collection bag, opens bag and places distal end of device into bag. Closes bag around distal end.			
Flushes water through lumen/channel. Using same syringe, flushes 10ml air through lumen/channel. Recaptures sample water in sample collection bag.			
Carefully removes sample collection bag and dips test strip into sample water for 5 seconds, ensuring that all three pads are completely immersed.			
Removes test strip and dabs edge of strip on absorbent surface.			
Using a timer, waits full 90 seconds, then compares pads on test strip to Control Color Chart.			
Records results for each pad on established log sheet.			
Verbalizes actions for failed result – based on institutional policy/protocol.			
Fills new syringe with 10 mL pre-packaged chlorine-free water.			
TESTING ENDOSCOPE VALVES AND/OR BIOPSY CAPS			
Places items into separate sterile containers.			
Adds exactly 10ml pre-packaged chlorine-free water to each container and closes each container securely.			
Gently shakes each container thoroughly.			
With one test strip per container, performs dip test of sample water (as above).			

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