

## It's the Little Things that Count: Clarifications to 2021 Bloodstream Infection Definitions

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### **Purpose**

Share the 2021 updates on Non-culture Based Testing (NCT) to meet Laboratory Confirmed Bloodstream Infection (LCBI) Criteria and provide an overview of the testing methodology used to meet Mucosal Barrier Injury Laboratory-Confirmed Bloodstream Infection criteria 2 and 3 (MBI-LCBI 2 and MBI LCBI 3)

## **Objectives**

At the completion of this presentation, you will:

- Know how to distinguish between culture based versus non-culture based methodology
- Recognize the testing methodology used to meet MBI-LCBI 2 and MBI-LCBI 3 criteria
- Receive clarification on meeting the Epidermolysis bullosa Central Line Associated
   Bloodstream Infection (CLABSI) exclusion

## **Key Definitions**

## What Exactly Does This Mean: Culture Based Testing?

Culturing requires that a specimen be inoculated to a culture media, incubated and observed for actual growth of microorganisms and can take several days to weeks for a final report depending upon the organism identified.

#### Patient of any age has a recognized bacterial or fungal pathogen, not included on the NHSN common LCBI 1 commensal list: If LCBI 1 Identified from one or more blood specimens obtained by a culture OR criteria is 2. Identified to the genus or species level by non-culture based microbiologic testing (NCT)\* met, methods (for example, T2 Magnetic Resonance [T2MR] or Karius Test). Note: If blood is consider collected for culture within 2 days before, or 1 day after the NCT, disregard the result of the MBI-LCBI 1 NCT and use only the result of the CULTURE to make an LCBI surveillance determination. If no blood is collected for culture within this time period, use the result of the NCT for LCBI surveillance determination. AND Organism(s) identified in blood is not related to an infection at another site (See Appendix B: Secondary BSI Guide). \*For the purposes of meeting LCBI-1, NCT is defined as a methodology that identifies an organism directly from a blood specimen without inoculation of the blood specimen to any culture media. For instance, NCT does not include identification by PCR of an organism grown in a blood culture bottle or any other culture media.

 An example of a culture media is blood culture collection bottles.

## What Exactly Does This Mean: Non-Culture Based Testing?

MBI-LCBI 1

- Non-culture based testing refers to identification of microorganisms using a method of testing other than a culture.
- An example of NCT methodology:
  - Polymerase Chain
     Reaction or PCR

LCBI 1

If LCBI 1

Criteria is met, consider

Patient of any age has a recognized bacterial or fungal pathogen, not included on the NHSN common commensal list:

1. Identified from one or more blood specimens obtained by a culture OR

2. Identified to the genus or species level by non-culture based microbiologic testing (NCT)\*

methods (for example, T2 Magnetic Resonance [T2MR] or Karius Test). Note: If blood is collected for culture within 2 days before, or 1 day after the NCT, disregard the result of the

surveillance determination.

#### AND

blood is collected for culture within this time period, use the result of the NCT for LCBI

NCT and use only the result of the CULTURE to make an LCBI surveillance determination. If no

Organism(s) identified in blood is not related to an infection at another site (See Appendix B: Secondary BSI Guide).

\*For the purposes of meeting LCBI-1, NCT is defined as a methodology that identifies an organism directly from a blood specimen without inoculation of the blood specimen to any culture media. For instance, NCT does not include identification by PCR of an organism grown in a blood culture bottle or any other culture media.

# Review of the 2021 Laboratory Confirmed Bloodstream Infection Criteria

# LCBI-1<br/>Criterion

Criterion							
Criterion	Comments and reporting instructions that follow the site-specific criteria provide further						
	explanation and are integral to the correct application of the criteria.						
	Once an LCBI determination is made, proceed to the MBI-LCBI definitions and determine if the corresponding MBI-LCBI criteria are also met (for example, after meeting LCBI 2, investigate for potential MBI-LCBI 2)						
LCBI 1	Patient of any age has a recognized bacterial or fungal pathogen, not included on the NHSN common						
If LCBI 1 criteria is met, consider MBI-LCBI 1	<ol> <li>Identified from one or more blood specimens obtained by a culture OR</li> <li>Identified to the genus or species level by non-culture based microbiologic testing (NCT)*     methods (for example, T2 Magnetic Resonance [T2MR] or Karius Test). Note: If blood is     collected for culture within 2 days before, or 1 day after the NCT, disregard the result of the     NCT and use only the result of the CULTURE to make an LCBI surveillance determination. If no     blood is collected for culture within this time period, use the result of the NCT for LCBI     surveillance determination.</li> </ol>						
	AND						
	Organism(s) identified in blood is not related to an infection at another site (See <u>Appendix B: Secondary BSI Guide</u> ).						
	*For the purposes of meeting LCBI-1, NCT is defined as a methodology that identifies an organism directly from a blood specimen without inoculation of the blood specimen to any culture media. For instance, NCT does not include identification by PCR of an organism grown in a blood culture bottle or any other culture media.						
	Notes:						
	<ol> <li>If a patient meets both LCBI 1 and LCBI 2 criteria, report LCBI 1 with the recognized pathogen entered as pathogen #1 and the common commensal as pathogen #2.</li> <li>No additional elements (in other words, no sign or symptom such as fever) are needed to meet LCBI 1 criteria; therefore, the LCBI 1 DOE will always be the collection date of the first positive blood specimen used to set the BSI IWP.</li> </ol>						

2021 NCT Clarification

- Examples of PCR testing results:
  - Example 1: Blood culture specimen is collected, and the specimen is inoculated into culture media. After a day of incubation, the media broth shows growth. A sample of the broth is used for PCR testing. The sample is identified as *Enterococcus faecalis*. Is this considered a non-culture based test?

- Examples of PCR testing results:
  - Example 2: Blood culture specimen is collected. PCR is performed directly on a sample of the collected blood specimen. *Candida albicans* is identified by PCR. Is this considered a non-culture based test?

- Example 1 with Rationale:
  - Example 1: Blood culture specimen is collected. The specimen is inoculated into a culture media broth. After a day of incubation, the media broth shows growth. A sample of the broth is used for PCR testing. The sample is identified as *Enterococcus faecalis*. Is this considered a non-culture based test?

No, this is not considered a non-culture based test.

Rationale: Although the organism is identified by PCR, the specimen is first inoculated into a culture broth, and there is subsequent growth. Inoculation into the media broth is considered a form of culture-based testing. As a result, you should use the guidance provided for culture-based testing to determine if LCBI-1 criterion is met. Because *E. faecalis* is a recognized pathogen no additional elements are needed to meet criterion 1. This is an LCBI-1 event.

- Example 2 with Rationale:
  - Example 2: Blood culture specimen is collected. PCR is performed directly on a sample of the collected blood specimen. Candida albicans is identified by PCR. Is this considered a non-culture based test?

This is considered a non-culture based test.

Rationale: The identification of *Candida albicans* is determined directly from a blood sample. The blood was not inoculated to media; there was not growth prior to the PCR testing. In this example NHSNs BSI protocol's surveillance definition of an NCT is met. The *Candida albicans* identified by an NCT method is eligible for use to determine if LCBI-1 criterion can be met.

LCBI 2

If LCBI 2 criteria is met, consider MBI-LCBI 2 Patient of any age has at least <u>one</u> of the following signs or symptoms: fever (>38.0°C), chills, or hypotension

#### AND

Organism(s) identified in blood is not related to an infection at another site (See Appendix B: Secondary BSI Guide).

#### AND

The same NHSN common commensal is identified by a culture, from two or more blood specimens collected on separate occasions (see Blood Specimen Collection).

Common Commensal organisms include, but are not limited to diphtheroids (Corynebacterium spp. not C. diphtheria), Bacillus spp. (not B. anthracis), Propionibacterium spp., coagulase-negative staphylococci (including S. epidermidis), viridans group streptococci, Aerococcus spp. Micrococcus spp. and Rhodococcus spp. For a full list of common commensals, see the Common Commensal tab of the NHSN Organisms List.

#### Notes:

- Criterion elements must occur within the 7-day IWP (as defined in <u>Chapter 2</u>)
  which includes the collection date of the positive blood specimen, the 3
  calendar days before and the 3 calendar days after.
- The two matching common commensal specimens represent a single element for use in meeting LCBI 2 criteria and the collection date of the <u>first</u> specimen is used to determine the BSI IWP.
- 3. At least one element (specifically, a sign or symptom of fever, chills or hypotension) is required to meet LCBI 2 criteria; the LCBI 2 DOE will always be the date the *first* element occurs for the first time during the BSI IWP, whether that be a sign or symptom or the positive blood specimen.

	6/1	Fever > 38.0 °C	LCBI 2 DOE = $6/1$
	6/2	No LCBI element	
	6/3	No LCBI element	
Single	6/4	S. epidermidis(1 of 2)	Date of $1^{1t}$ diagnostic test = $6/4$
element	6/5	S. epidermidis(2 of 2)	
	6/6	No LCBI element	
	6/7	No LCBI element	

LCBI-2
definition
remains
the same
for 2021

LCBI 3 If LCBI 3 criteria is met, consider MBI-LCBI Patient ≤ 1 year of age has at least <u>one</u> of the following signs or symptoms: fever (>38.0°C), hypothermia (<36.0°C), apnea, or bradycardia

#### AND

Organism(s) identified in blood is not related to an infection at another site (See <u>Appendix B: Secondary BSI Guide</u>).

#### AND

The same NHSN common commensal is identified by a culture, from two or more blood specimens collected on separate occasions (see Blood Specimen Collection).

Common Commensal organisms include, but are not limited to diphtheroids (Corynebacterium spp. not C. diphtheria), Bacillus spp. (not B. anthracis), Propionibacterium spp., coagulase-negative staphylococci (including S. epidermidis), viridans group streptococci, Aerococcus spp. Micrococcus spp., and Rhodococcus spp. For a full list of common commensals, see the Common Commensal tab of the NHSN organisms list.

#### Notes:

- Criterion elements must occur within the 7-day IWP (as defined in <u>Chapter 2</u>)
  which includes the collection date of the positive blood specimen, the 3 calendar
  days before and the 3 calendar days after.
- The two matching common commensal specimens represent a single element for use in meeting LCBI 3 criteria and the date of the <u>first</u> is used to determine the BSI IWP.
- 3. At least one element (specifically, a sign or symptom of fever, hypothermia, apnea or bradycardia) is required to meet LCBI 3 criteria; the LCBI 3 DOE will always be the date the *first* element occurs for the first time during the BSI IWP whether that be a sign or symptom or the positive blood specimen.

	5/31	No LCBI element	
	6/1	No LCBI element	
	6/2	No LCBI element	
Single	6/3	S. epidermidis (1 of 2)	Date of 1st diagnostic test = 6/3
element			LCBI DOE = 6/3
	6/4	S. epidermidis (1 of 2)	
	6/5	Apnea documented	
	6/6	No LCBI element	

LCBI-3 definition remains the same for 2021

## **Examples of How to Meet LCBI-1 Criterion**

Patient of any age has a recognized bacterial or fungal pathogen, not included on the NHSN common commensal list:

- Identified from one or more blood specimens obtained by a culture OR.
- 2. Identified to the genus or species level by non-culture based microbiologic testing (NCT) methods (for example, T2 Magnetic Resonance [T2MR] or Karius Test). Note: If blood is collected for culture within 2 days before, or 1 day after the NCT, disregard the result of the NCT and use only the result of the CULTURE to make an LCBI surveillance determination. If no blood is collected for culture within this time period, use the result of the NCT for LCBI surveillance determination.

In this example, *S. aureus* is **identified directly from a blood sample** by an NCT methodology. So, LCBI-1 criterion is met on 2/6. The infection window period (IWP) is 2/3-2/9, and a BSI repeat infection timeframe is established from 2/6-2/19. This is a CLABSI event because there was an eligible central line on the DOE.

Rationale: The identification of *S. aureus* is determined by the NCT. Since there is no identification of an organism using culture-based testing <u>2 days before or 1 day after</u>, the NCT result meets LCBI-1 criterion.

See Page 4-7 of the 2021 BSI chapter

Hospital		First Diagnostic				
Day	Date	Test	IWP	DOE	RIT	Notes
1	2/3					Admitted
2	2/4					
						Central Line
						inserted
3	2/5					
		+PCR directly				
		from a blood				
		sample	W	DOE		
	0.0	Staphylococcu	Р			
4	2/6	s aureus	•			
5	2/7					
6	2/8				R	
7	2/9				ï	
8	2/10				Ť	
9	2/11					
10	2/12					
11	2/13					
12	2/14					
13	2/15					
14	2/16					
15	2/17					
16	2/18					
17	2/19					
18	2/20					
19	2/21					

Patient of any age has a recognized bacterial or fungal pathogen, not included on the NHSN common commensal list:

- 1. Identified from one or more blood specimens obtained by a culture OR
- 2. Identified to the genus or species level by non-culture based microbiologic testing (NCT) methods (for example, T2 Magnetic Resonance [T2MR] or Karius Test). Note: If blood is collected for culture within 2 days before, or 1 day after the NCT, disregard the result of the NCT and use only the result of the CULTURE to make an LCBI surveillance determination. If no blood is collected for culture within this time period, use the result of the NCT for LCBI surveillance determination.

**LCBI-1 criterion is met on 2/6.** The infection window period (IWP) is 2/3-2/9, and a BSI repeat infection timeframe is established from 2/6-2/19. The organism reported is *K. pneumoniae*. This is a CLABSI event because there was an eligible central line on the DOE.

Rationale: Because the blood culture identifying *K. pneumoniae* is collected within the 2 days before or 1 day after the +NCT, the NCT is disregarded. The only result used is the positive culture result for *K. pneumoniae*. The identification of *E. cloacae* by PCR would not change the DOE nor would the organism be added to the event since the NCT result is disregarded.

		First				
Hospital		Diagnostic				
Day	Date	Test	IWP	DOE	RIT	Notes
1	2/3					Admitted
2	2/4					Central Line inserted
3	2/5					
4	2//6	+Blood culture: <i>Klebsiella</i> <i>pneumoniae</i> identified	I W P	DOE		
		+PCR on blood sample: <i>Enterobacter</i> <i>cloacae</i> identified			R I T	
5	2/7					
6	2/8					
7	2/9					
8						
9	2/11					
10						
11	2/13					
12						
13 14						
15						
16						
17	2/10					
18						
19						
10	2121					

Patient of any age has a recognized bacterial or fungal pathogen, not included on the NHSN common commensal list:

- Identified from one or more blood specimens obtained by a culture OR.
- 2. Identified to the genus or species level by non-culture based microbiologic testing (NCT) methods (for example, T2 Magnetic Resonance [T2MR] or Karius Test). Note: If blood is collected for culture within 2 days before, or 1 day after the NCT, disregard the result of the NCT and use only the result of the CULTURE to make an LCBI surveillance determination. If no blood is collected for culture within this time period, use the result of the NCT for LCBI surveillance determination.

## LCBI-1 criterion is not met on 2/6 and LCBI-2 criterion is not met on 2/7.

Rationale: The identification of *Staph capitis* by culture occurs 2 days before or 1 day after, the positive PCR. Because *Staph capitis* is identified by culture, this result must be used to determine if LCBI criteria is met. Because *Staph capitis* is a single common commensal, the organism does not meet LCBI-2 criterion. Both the NCT and culture results are disregarded. There is no BSI or CLABSI event to report.

Hospital				DO		
Day	Date	First Diagnostic Test	IWP	E	RIT	Notes
1	2/3					Admitted
2	2/4					Central
						Line
						inserted,
						MICU
3	2/5					
		LDOD dine officers of				
		+PCR directly from a				
	2/6	blood sample identified				
4	2/6	Lactobacillus				
		+Blood culture identified				
		a single <i>Staphylococcus</i>				
5		capitis				
6	2/8	Fever				
7	2/9					
8						
9	2/11					
10						
11	2/13					
12	2/14					
13						
14	2/16					

Patient of any age has a recognized bacterial or fungal pathogen, not included on the NHSN common commensal list:

- Identified from one or more blood specimens obtained by a culture OR.
- 2. Identified to the genus or species level by non-culture based microbiologic testing (NCT) methods (for example, T2 Magnetic Resonance [T2MR] or Karius Test). Note: If blood is collected for culture within 2 days before, or 1 day after the NCT, disregard the result of the NCT and use only the result of the CULTURE to make an LCBI surveillance determination. If no blood is collected for culture within this time period, use the result of the NCT for LCBI surveillance determination.

#### LCBI-1 criterion is not met on 2/6 or 2/7

Rationale: The identification of a blood culture occurs 2 days before or 1 day after, the positive PCR. The culture result must be used to determine if LCBI criteria is met. Because there is no growth by blood culture, there is no BSI or CLABSI event to report.

Hospital		First Diagnostic				
Day	Date		IWP	DOE	RIT	Notes
1	2/3					Admitted
2						Central Line inserted, MICU
3	2/5					
4	2/6	+PCR directly from a blood sample identified Pseudomonas species				
5		Blood culture No Growth				
6	2/8					
7	2/9					
	2/10					
9						
10						
11						
	2/14					
	2/15 2/16					
14	2/10					

# **Examples of How to Meet LCBI-2 or LCBI-3**Criterion

Patient of any age has at least <u>one</u> of the following signs or symptoms: fever (>38.0°C), chills, or hypotension

#### AND

Organism(s) identified in blood is not related to an infection at another site (See Appendix B: Secondary BSI Guide).

#### AND

The same NHSN common commensal is identified by a culture, from two or more blood specimens collected on separate occasions (see <u>Blood Specimen Collection</u>).

Common Commensal organisms include, but are not limited to diphtheroids (Corynebacterium spp. not C. diphtheria), Bacillus spp. (not B. anthracis), Propionibacterium spp., coagulase-negative staphylococci (including S. epidermidis), viridans group streptococci, Aerococcus spp. Micrococcus spp. and Rhodococcus spp. For a full list of common commensals, see the Common Commensal tab of the NHSN Organisms List.

#### LCBI-2 criterion is not met on 2/6.

Rationale: The +NCT result is not used as a companion culture. Only a single common commensal is identified using culture-based testing. LCBI-2 criterion is not met.

See Page 4-8 of the 2021 BSI chapter

Hospital		First Diagnostic				
Day	Date	Test	IWP	DOE	RIT	Notes
1	2/3					Admitted
2	2/4					Central Line inserted, MICU
3	2/5					
4		+Blood culture Staphylococcus epidermidis				
		+PCR Staphylococcus				
5	2/7	epidermidis				
6	2/8	Fever				
7	2/9					
8	2/10					
9	2/11					
10	2/12					
11	2/13					
12	2/14					
13	2/15					
14	2/16					

Patient ≤ 1 year of age has at least <u>one</u> of the following signs or symptoms: fever (>38.0°C), hypothermia (<36.0°C), apnea, or bradycardia

#### AND

Organism(s) identified in blood is not related to an infection at another site (See <u>Appendix B: Secondary BSI Guide</u>).

#### AND

The same NHSN common commensal is identified by a culture, from two or more blood specimens collected on separate occasions (see <u>Blood Specimen Collection</u>).

Common Commensal organisms include, but are not limited to diphtheroids (Corynebacterium spp. not C. diphtheria), Bacillus spp. (not B. anthracis), Propionibacterium spp., coagulase-negative staphylococci (including S. epidermidis), viridans group streptococci, Aerococcus spp. Micrococcus spp., and Rhodococcus spp. For a full list of common commensals, see the Common Commensal tab of the NHSN organisms list.

#### LCBI-3 criterion is not met on 2/7.

Rationale: The +NCT result identifying *Staph hominis* is not eligible for use to meet LCBI-3 criterion. The specimen collection requirement for LCBI-3 criterion requires identification of companion cultures by culture from two or more blood specimens. NCT methodology is not used.

		First				
Hospital	Data	Diagnostic	IVA/D	DOE	БІТ	Natas
Day	Date	Test	IWP	DOE	RIT	Notes
1	2/3					Admitted
2	2/4					
						Central Line
						inserted,
						MICU
3	2/5					
4	2/6					
		+PCR				
		Staphylococcus				
5	2/7	hominis				
6	2/8	Apnea				
_	0.40					
7 8	2/9 2/10					
9	2/10					
10	2/11					
11	2/12					
12	2/14					
13	2/15					
14	2/16					

## **NCT Eligibility and Reminders**

- NCT methodology referred to in the BSI protocol is a testing methodology identifying an organism directly from a blood sample.
- NCT methodology is only used to meet LCBI-1 criterion.
- Test results from NCT methodologies are only available for use in meeting LCBI-1 when the organism is identified to the genus or genus and species level.

 Positive blood culture results from culture -based testing is the only testing methodology used to meet LCBI-2 and-LCBI-3. NCT is not used.

Clarification for Mucosal Barrier Injury Laboratory Confirmed Bloodstream Infection Criteria 2 and 3 (MBI-LCBI)

## MBI LCBI-2 and MBI LCBI 3 Criteria Requirements

 MBI-LCBI is a subset of the LCBI criteria; therefore, a BSI event must fully meet an LCBI criterion before evaluating for the corresponding MBI-LCBI criteria.

MBI-LCBI date of event (DOE) will always be the date the prerequisite LCBI criteria [is] met. Abnormal ANC and WBC values reflect risk factors for acquiring an MBI-LCBI, not symptoms of infection and therefore are not used in DOE determinations.

Clarification in the 2021 BSI summary updates address identification of an organism by <u>culture only</u> for MBI LCBI-2 and MBI LCBI-3 criteria.

### MBI LCBI-2 and 3 Criteria Requirements

January 2021 Device-associated Module Table 2: Mucosal Barrier Injury Laboratory-Confirmed Bloodstream Infection (MBI-LCBI) Must meet one of the following MBI-LCBI criteria An MBI-LCBI is a subset of the LCBI criteria; therefore, a BSI event must fully meet an LCBI criterion before evaluating for the corresponding MBI-LCBI criteria. The MBI-LCBI DOE will always be the date the prerequisite LCBI criteria was met. Abnormal ANC and WBC values reflect risk factors for acquiring an MBI-LCBI, not symptoms of infection and therefore are not used in DOE determinations. MBI-LCBI 1 MBI-LCBI 2 MBI-LCBI 3 Patient of any age fully meets Patient of any age fully meets LCBI Patient ≤1 year of age fully meets LCBI 1 criterion LCBI 3 criterion with at least one blood specimen with at least two matching blood specimens with ONLY intestinal organisms with ONLY Viridans Group Streptococcus and/or Rothia spp.alone but from the NHSN MBI organism list\* no other organisms + identified by culture or nonculture based microbiologic identified by culture testing method Patient meets at least one of the following: 1. Is an allogeneic hematopoietic stem cell transplant recipient within the past year with one of the following documented during same hospitalization as positive blood specimen: a. Grade III or IV gastrointestinal graft versus host disease [GI GVHD] b. ≥1-liter diarrhea in a 24-hour period (or ≥20 mL/kg in a 24-hour period for patients <18 years of age) with onset on or within the 7 calendar days before the date the positive blood specimen was collected. Is neutropenic, defined as at least two separate days with ANC\* and/or WBC values <500</li> cells/mm3 collected within a 7-day time period which includes the collection date of the positive blood specimen, the 3 calendar days before and the 3 calendar days after (See Table 5). 1. If a patient meets both MBI-LCBI 1 and MBI-LCBI 2 criteria (specifically has Viridans Group Streptococcus or Rothia spp. plus only other MBI organisms in the blood specimen), report 4 - 10

See Page 4-10 of the 2021 BSI chapter

# CLABSI Exclusion Reporting Criteria Clarification: Epidermolysis bullosa (EB)

## Closer look at Epidermolysis bullosa

Epidermolysis bullosa CLABSI exclusion 2020

• If during the current admission, there is a diagnosis of EB report such event(s), marking the EB field as "Yes." Epidermolysis bullosa CLABSI exclusion **2021** 

If during the current admission, there is documentation of a diagnosis of EB report such an event, marking the EB field as "Yes."

## Closer look at Epidermolysis bullosa

If during the current admission, there is documentation of a diagnosis of EB report such an event, marking the EB field as "Yes."

- Clarification note is provided regarding the forms of EB and the age groups eligible for use to meet the EB CLABSI exclusion.
  - The Epidermolysis bullosa (EB) CLABSI exclusion is limited to the genetic forms of EB in the pediatric population.

## **Summary of LCBI Updates and CLABSI Exclusions**

 NCT methodology referred to in the BSI protocol is a testing methodology identifying an organism directly from a blood sample.

 MBI LCBI-2 and MBI LCBI-3 criteria require identification of an organism by culture only.

- The EB CLABSI exclusion is met, if during the current admission, there is documentation of a diagnosis of EB
  - The EB CLABSI exclusion is limited to the genetic forms of EB in the pediatric population.

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