Policy Number: 1954
Manual Name: Infection Prevention
Policy Name: C. difficile Testing Process and Algorithm
Last Revised: 11/08/2022

Clostridium difficile
Testing Process and Algorithm

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Policy Type

- ☐ Entity Governance Policy
- ☐ Entity Policy
- ☒ Entity Departmental Policy
- ☐ Governance Policy
- ☐ Corporate Policy
- ☐ Corporate Departmental Policy

Policy Scope

- ☐ Summa Health (Corporate)
- ☐ Summa Health Network
- ☐ Summa Health Medical Group
- ☐ SummaCare
- ☒ Summa Health System (Hospitals)
- ☐ New Health Collaborative
- ☐ Department: _____

1.0 Purpose:

1.1 To accurately and quickly identify patients who are infected with acute, active *Clostridium difficile (C. difficile)* infection.

1.2 To utilize appropriate isolation precautions until transmission risk is reduced with inpatient and select outpatient Summa Health System areas: Emergency Departments and Clinical Decision Units.

2.0 Background:

2.1 *C. difficile* bacteria can produce two toxins, designated A and B, that have pathogenic effects in humans. Antibiotic-associated pseudomembranous colitis has been shown to result from the action of these two toxins.

2.2 *C. difficile* disease has been associated with clindamycin/cephalosporin use but it is now recognized that pseudomembranous colitis can follow administration of any antibiotic regimen.

2.3 *C. difficile* community and healthcare onset of disease incidence is reported to the National Health and Safety Network (NSHN) for ranking and patient safety metrics for Summa Health System.

3.0 Scope

3.1 Summa Health System

4.0 Definitions:

4.1 Inpatient – Any person physically located and bedded in an inpatient location regardless of status of patient (observation, etc.).

4.2 Outpatient – Any person physically located and bedded in an outpatient location: emergency department or clinical decision unit regardless of status (inpatient, etc.).

4.3 Healthcare onset (HO) - C. difficile positive isolate collected from a patient on or after calendar day 4 of inpatient admission.

4.4 Community onset (CO) - C. difficile positive isolate collected from a patient on calendar day 1 – 3 of inpatient or outpatient admission to Summa Health System.

4.5 Symptomatic – Defined as a patient having **one or more** of the following symptoms 72 hours prior to collection of eligible stool specimen:

- 4.5.1 Nausea, vomiting, abdominal pain, fever (>38.1), or WBC (> 10.7).
- 4.5.2 Liquid or watery stool – Stool that conforms to the shape of the container without manual manipulation and contains no solid pieces. Bristol type 7 only (Appendix 1).
- 4.5.3 Diarrhea – Liquid and/or watery stools > 3 separately documented in last 24 hours.
- 4.5.4 New onset – Not baseline for patient.

4.5.5 Confounding medication – A medication or consumed substance that when administered has the effect of inducing or promoting loose, watery stool without likely infectious source.

4.5.5.1 Examples: Stool softeners, laxatives, bowel prep, oral contrast, or lactulose.

4.5.5.2 Tube feed is a confounding medication but cannot be stopped for 72 hours.

4.6 Eligible stool specimen – A liquid or watery stool transported to the laboratory within 24 hours of collection.

4.7 Molecular C. difficile test – Polymerase chain reaction (PCR) or nucleic acid amplification test (NAAT). This test is specific for toxigenic strains **but does not test for active toxin** production and also detects asymptomatic carriers of toxigenic C difficile.

4.8 GDH C. difficile test – glutamate dehydrogenase (GDH) antigen test uses antibodies to test for the presence of the GDH enzyme, a protein present in all C. difficile isolates.

4.9 EIA C. difficile test – Enzyme immunoassay (EIA) able to detect C. difficile toxins A and B.

4.10 Multi-step C. difficile testing process – The use of a NAAT based assay with reflex to another confirmatory assay if first NAAT test is detected to confirm likely acute infection with toxigenic C. difficile. The final test performed and resulted will determine toxigenic C. difficile status of the patient.

4.11 C. difficile colonization – patient tests positive but not experiencing active disease/symptoms of C. difficile.

4.12 C. difficile infection – patient tests positive and experiencing active disease/symptoms of C. difficile.

5.0 Policy:

5.1 Any order for *C. difficile* testing is required to meet all four separate clinical criteria prior to an eligible stool sample going to the laboratory.

5.1.1 **Criteria 1** – Patient has new onset liquid or watery stool – defined as not the patient's typical baseline and adheres to Bristol type 7 definition conforming to the shape of the container. **DO NOT SEND FORMED STOOL.**

5.1.2 **Criteria 2** – Patient has liquid and/or watery stools > 3 separately documented in last 24 hours prior to order for *C. difficile*. The stools must be documented in the patient's electronic medical record in flowsheets or notes.

5.1.3 **Criteria 3** – Patient has not been ordered or administered any confounding medications within 72 hours of order: laxatives, enemas, bowel preps, or lactulose. Ensure patient has these medications held for at least 72 hours. Tube feeding is also a confounding medication but cannot be held like the other medications.

5.1.4 **Criteria 4** – Patient has at least one of the following signs or symptoms documented in electronic medical record: fever > 100.4, nausea, vomiting, abdominal pain, or leukocytosis >10.7.

5.1.5 **WHEN** all four of the above criteria are met on or after day four of calendar admission to inpatient location, order *C. difficile* test.

5.2 Physicians or other clinical staff are to adhere to the criteria. The stool specimen will be reviewed with the ordering physician and may be rejected when ordered after calendar day three of admission. See Appendix 2.

5.3 Confounding medications must be held for 72 hours.
5.3.1 Excludes tube feed

5.4 Exclusions to policy:
5.4.1 Emergency room visits, Outpatient visits.
5.4.2 First three calendar days of admission.

5.5 All eligible stool samples will run initially as a PCR assay followed by reflex to GDH (antigen) and EIA (toxin tests). See interpretation below for HO and CO determination based upon the last test resulted.

PCR	GDH Antigen	EIA-Toxin	Isolation
Negative			Testing is consistent with no detection of C. difficile infection. Discontinue isolation
Positive	Negative	Negative	Colonization, continue with enhanced contact isolation
Positive	Positive	Negative	Indeterminate, may represent colonization or infection. Continue with enhanced contact isolation
Positive	Positive	Positive	Testing is consistent with C difficile infection. Continue with enhanced contact isolation

5.6 When using a multi-step testing algorithm for CDI on the same unformed stool specimen, the finding of the last test performed on the specimen that is documented in the patient medical record will determine if the CDI positive laboratory assay definition is met.

6.0 Procedure:

6.1 Initiate enhanced contact precautions in electronic medical record for all patients suspected or confirmed having C. difficile

6.2 For all patients suspected or confirmed of having C. difficile, order cart and post yellow isolation sign outside patient room.

6.2.1 See enhanced contact precautions in Infection Control Manual. http://summaworks/plyproc/InfectionPrevention/1911-Transmission-Based%20Precautions.docx

6.3 When evaluating patients for other causes of diarrhea, consider ordering the GI PCR panel.

6.3.1 Implement and follow enhanced contact isolation precautions in Infection Prevention Manual. http://summaworks/plyproc/InfectionPrevention/1911-Transmission-Based%20Precautions.docx

6.4 Send all eligible stool specimens to the lab when clinically appropriate and only when adhering to all four (4) order criteria on or after day four of calendar admission.

6.5 Ensure stool is adhering to the sides of the sterile specimen container. Do not swish or swirl stool to comply with this.

6.6 Do not delay transport of eligible stool specimen to the microbiology lab.

6.7 Wash hands with soap and water upon doffing gown and gloves upon exit of patient care room.

6.8 Clinical test may be discontinued if does not adhere to Summa Health System policy and order criteria.

7.0 Responsibilities and Authorities:

7.1 Infection prevention will update and ensure accuracy of policy elements annually or with any microbiology assay updates as needed.

7.2 Quality department directors, unit directors, and other relevant leadership are notified when HO C. difficile infections exceed baseline for any clinical area for ACA process to be initiated on a unit level.

8.0 Records:

8.1 None.

9.0 References:

9.1 CDC (2022). Retrieved from https://www.cdc.gov/cdiff/clinicians/resources.html

9.2 Labcorp (2022). Retrieved from https://www.labcorp.com/tests/086207/i-clostridium-diffC. difficile-i-toxins-a-and-b-eia

9.3 CDC (NHSN). (2022). Retrieved from MDRO & CDI Protocol (cdc.gov)

9.4 S. J. Lewis & K. W. Heaton (1997) Stool Form Scale as a Useful Guide to Intestinal Transit Time, Scandinavian Journal of Gastroenterology, 32:9, 920-924, DOI: 10.3109/00365529709011203

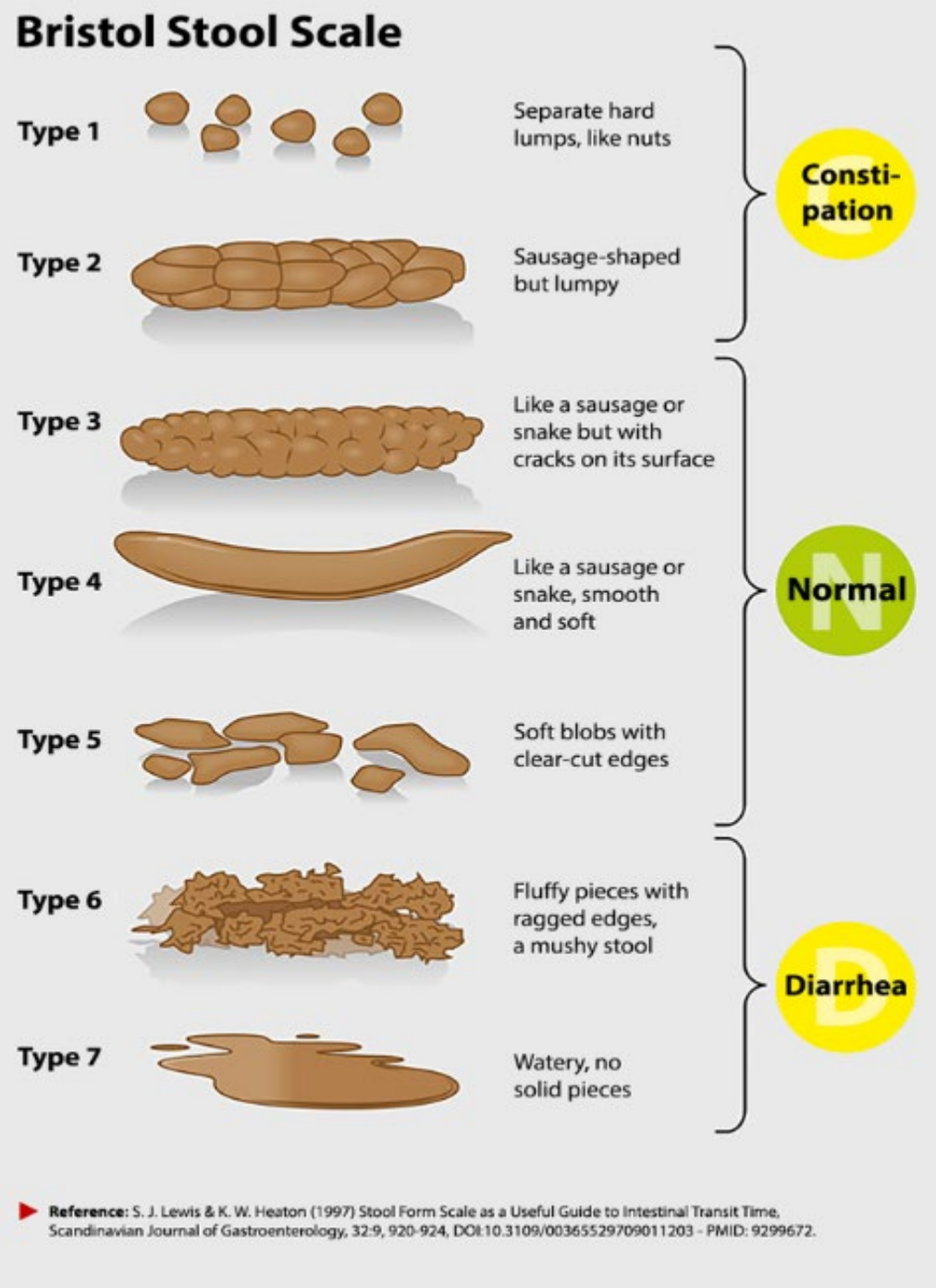
9.5 Stuart Johnson, Valéry Lavergne, Andrew M Skinner, Anne J Gonzales-Luna, Kevin W Garey, Ciaran P Kelly, Mark H Wilcox, Clinical Practice Guideline by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA): 2021 Focused Update Guidelines on Management of Clostridioides diffC. difficile Infection in Adults, Clinical Infectious Diseases, Volume 73, Issue 5, 1 September 2021, Pages e1029–e1044, https://doi.org/10.1093/cid/ciab549

9.6 McDonald, L. C., Gerding, D. N., Johnson, S., Bakken, J. S., Carroll, K. C., Coffin, S. E., Dubberke, E. R., Garey, K. W., Gould, C. V., Kelly, C., Loo, V., Shaklee Sammons, J., Sandora, T. J., & Wilcox, M. H. (2018). Clinical Practice Guidelines for Clostridium diffC. difficile Infection in Adults and Children: 2017 Update by the Infectious Diseases Society of America (IDSA) and Society for Healthcare Epidemiology of America (SHEA). Clinical infectious diseases: an official publication of the Infectious Diseases Society of America, 66(7), e1–e48. https://doi.org/10.1093/cid/cix1085

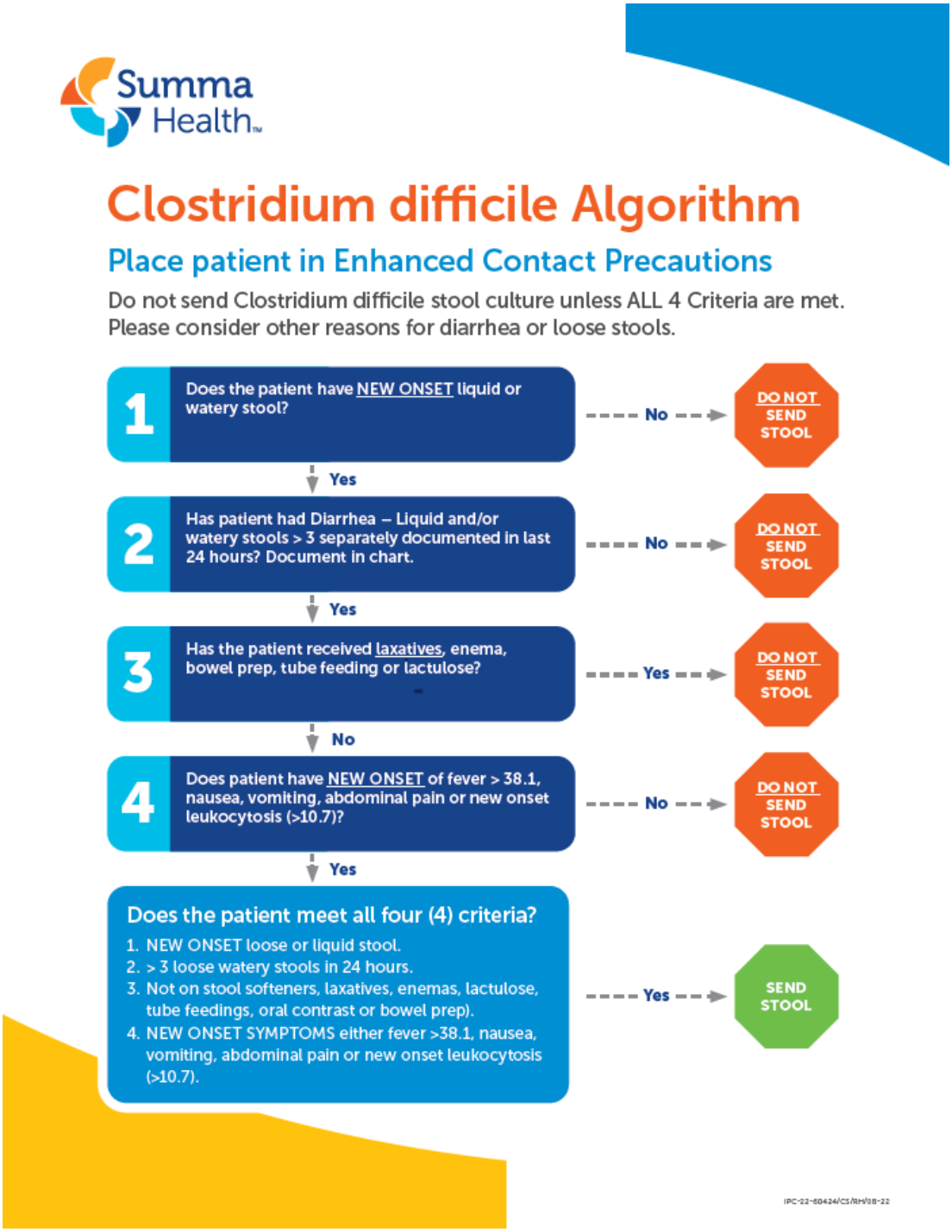
10.0 Key Words or Aliases (Optional):

10.1 *C. difficile*

Appendix 1.


Bristol Stool Scale
Type 1
Separate hard lumps, like nuts
Type 2
Sausage-shaped but lumpy
Consti-pation
Type 3
Like a sausage or snake but with cracks on its surface
Type 4
Like a sausage or snake, smooth and soft
Type 5
Soft blobs with clear-cut edges
Normal
Type 6
Fluffy pieces with ragged edges, a mushy stool
Type 7
Watery, no solid pieces
Diarrhea
Reference: S. J. Lewis & K. W. Heaton (1997) Stool Form Scale as a Useful Guide to Intestinal Transit Time, Scandinavian Journal of Gastroenterology, 32:9, 920-924, DOI:10.3109/00365529709011203 - PMID: 9299672.

Appendix 2.


Summa Health
Clostridium difficile Algorithm
Place patient in Enhanced Contact Precautions
Do not send Clostridium difficile stool culture unless ALL 4 Criteria are met.
Please consider other reasons for diarrhea or loose stools.
1
Does the patient have NEW ONSET liquid or watery stool?
No
DO NOT SEND STOOL
Yes
2
Has patient had Diarrhea – Liquid and/or watery stools > 3 separately documented in last 24 hours? Document in chart.
No
DO NOT SEND STOOL
Yes
3
Has the patient received laxatives, enema, bowel prep, tube feeding or lactulose?
Yes
DO NOT SEND STOOL
No
4
Does patient have NEW ONSET of fever > 38.1, nausea, vomiting, abdominal pain or new onset leukocytosis (>10.7)?
No
DO NOT SEND STOOL
Yes
Does the patient meet all four (4) criteria?
1. NEW ONSET loose or liquid stool.
2. > 3 loose watery stools in 24 hours.
3. Not on stool softeners, laxatives, enemas, lactulose, tube feedings, oral contrast or bowel prep).
4. NEW ONSET SYMPTOMS either fever >38.1, nausea, vomiting, abdominal pain or new onset leukocytosis (>10.7).
Yes
SEND STOOL