Complete Summary

GUIDELINE TITLE

Guidelines for laboratory testing and result reporting of antibody to hepatitis C virus.

BIBLIOGRAPHIC SOURCE(S)

Alter MJ, Kuhnert WL, Finelli L. Guidelines for laboratory testing and result reporting of antibody to hepatitis C virus. Centers for Disease Control and Prevention. MMWR Recomm Rep 2003 Feb 7;52(RR-3):1-13, 15. [30 references] PubMed

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SCOPE

DISEASE/CONDITION(S)

Hepatitis C virus infection

GUIDELINE CATEGORY

Evaluation
Screening

CLINICAL SPECIALTY

Infectious Diseases
Internal Medicine
Pathology
Preventive Medicine

INTENDED USERS

Clinical Laboratory Personnel
Health Care Providers
Hospitals
Public Health Departments

GUIDELINE OBJECTIVE(S)

To improve the accuracy and utility of reported anti-hepatitis C virus (HCV) test results for counseling and medical evaluation of patients by health-care professionals and for surveillance by public health departments

TARGET POPULATION

Individuals at risk for hepatitis C virus infection

INTERVENTIONS AND PRACTICES CONSIDERED

Anti-Hepatitis C Virus (HCV) Screening Assays and Their Interpretation

1. Enzyme immunoassays (EIA)
    - Abbott HCV EIA
    - ORTHO® HCV Version 3.0 ELISA
2. Enhanced chemiluminescence assay (CIA)
    - VITROS® Anti-HCV assay

Supplemental Tests and Their Interpretation

1. Serologic anti-HCV assay
    - Chiron RIBA® HCV 3.0
2. Nucleic acid tests
    - AMPLICOR® Hepatitis C Virus Test, version 2.0
    - COBAS AMPLICOR® Hepatitis C Virus Test, version 2.0

MAJOR OUTCOMES CONSIDERED

Accuracy of hepatitis C virus tests

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Analysis of early versions of anti-hepatitis C virus (HCV) enzyme immunoassay (EIA) results from volunteer blood donors indicated that average repeatedly reactive signal to cut-off (s/co) ratios could be used to predict supplemental test-positive results. Similar data from volunteer blood donors were generated by

using HCV Version 3.0 ELISA, for which the average s/co ratios of 24,700 samples repeatedly reactive for anti-HCV were compared with their recombinant immunoblot assay (RIBA) 3.0 results (Susan Stramer, Ph.D., American Red Cross, personal communication, March 1999). Overall, 64.0% were RIBA-positive. The proportion that tested RIBA-positive was 5.8% for samples with an average s/co ratio 1.0-2.9; 37.1% for those with average s/co ratio 3.0-3.4; 67% for those with average s/co ratio 3.5-3.7; 88.1% for those with average s/co ratio 3.8-3.9; and 94.1% for those with average s/co ratio $\geq$4.0.

Additional data from other populations were generated by the Centers for Disease Control and Prevention (CDC) to determine if a specific s/co ratio could be identified that would predict a true antibody-positive result $\geq$95% of the time, regardless of the anti-HCV prevalence or characteristics of the population being tested. The anti-HCV screening tests evaluated were the two Food and Drug Administration-licensed EIAs, HCV EIA 2.0 and HCV Version 3.0 ELISA, and the one FDA-approved CIA, VITROS Anti-HCV assay.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Enzyme Immunoassays (EIAs)

All specimens with EIA screening-test-positive results were tested by recombinant immunoblot assay (RIBA) 3.0, and a sample of screening-test-positive specimens were tested for hepatitis C virus (HCV) ribonucleic acid (RNA) by $\geq$2 of the following nucleic acid test (NAT) methods: transcription-mediated amplification (TMA) (Procleix™, Chiron Corporation, Emeryville, California); AMPLICOR; and nested reverse transcriptase-polymerase chain reaction (RT-PCR). Test results were used from serum samples that had been collected as part of the Center for Disease Control and Prevention (CDC)-sponsored anti-HCV seroprevalence studies that were conducted among different groups of asymptomatic persons (Robert Gunn, M.D., San Diego County Department of Health and Human Services Agency; Steven Harris, M.D., Travis County, Texas Department of Health; Lu-Yu Hwang, M.D., University of Texas-Houston School of Public Health; Leslie Tobler, Ph.D., Blood Centers of the Pacific, San Francisco; Gayle Shimokura, University of

North Carolina at Chapel Hill School of Public Health; Isaac Weisfuse, M.D., New York City Department of Health and Mental Hygiene, personal communications, 2001-2002; CDC, unpublished data, 2002). Anti-HCV prevalences ranged from 0.8% to 25% (see Table 2 in the original guideline document).

Chemiluminescence Immunoassay (CIA)

The relation between signal to cut-off (s/co) ratios and RIBA 3.0 results also was evaluated for specimens that were screening-test-positive by CIA (i.e., reactive by VITROS Anti-HCV) from four groups. These included a group of 162 volunteer blood donors with substantially low anti-HCV prevalence (Leslie Tobler, Ph.D., Blood Centers of the Pacific, San Francisco, personal communication, September 2002), a group of 163 persons with low anti-HCV prevalence (college students, persons in the general population, and health-care workers as described previously), a group of 219 hemodialysis patients with intermediate anti-HCV prevalence (as described previously), and a group of 689 hospital-based patients with high anti-HCV prevalence (signs or symptoms of liver disease or risk factors for HCV infection) (D. Robert Dufour, M.D., VA Medical Center, Washington, D.C., and Michael De Lucia, Ortho-Clinical Diagnostics, personal communications, September 2002).

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

To assist laboratories in assessing the potential financial impact of implementing reflex supplemental testing for screening-test-positive samples with low signal to cut-off (s/co) ratios, the incremental costs associated with such testing were estimated for three hypothetical populations of 10,000 persons each, representing anti-hepatitis C virus (HCV) prevalences of 2%, 10%, and 25%, respectively (similar to those of the groups evaluated previously). For each population, the costs of performing the screening test (by using enzyme immunoassays [EIAs] as the example) and each of two different supplemental testing schemes (schemes 1 and 2) were compared with the cost of performing only the screening test (base scheme).

All schemes included performing a screening EIA on each sample and repeating initially reactive specimens in duplicate. Scheme 1 also included recombinant immunoblot assay (RIBA) testing on all screening-test-positive samples with average s/co ratios <3.8, and scheme 2 included nucleic acid test (NAT) testing on all screening-test-positive samples with average s/co ratios <3.8, followed by RIBA on those that were NAT-negative.

The increased costs for schemes 1 and 2 were calculated per sample tested compared with the base scheme. For RIBA and NAT, minimum and maximum

costs were estimated; minimum costs were defined as costs for reagents only, and maximum costs were defined as costs incurred for tests performed by a referral laboratory. The following assumptions were made:

- The percentage of initially reactive samples that were repeatedly reactive (screening-test-positive) was assumed to be 90% in the groups with anti-HCV prevalences of 2% and 10%, and 95% in the group with anti-HCV prevalence of 25%.
- The proportion of screening-test-positive samples with average s/co ratios <3.8 and the proportion of such samples that tested RIBA-positive for each population was derived.
- The proportion of screening-test-positive samples with average s/co ratios <3.8 that were NAT-positive was derived for the populations with anti-HCV prevalences of 2% and 10%. For the population with a prevalence of 25%, this proportion was assumed to be zero (on the basis of data from high-prevalence hospital-based patients).

Costs were estimated as follows and do not include personnel time or additional equipment:

- $5/sample for initial screening test
- $15/sample for those testing initially reactive and repeated in duplicate
- $65-$158/sample tested with RIBA
- $50-$295/sample tested with a NAT

Compared with performing only the screening test, performing reflex RIBA testing on all screening-test-positive samples with average s/co ratios <3.8 (scheme 1) increases the cost of testing per sample for immunocompetent populations from a minimum of 5%-12% ($0.41-$0.66) to a maximum of 13%-30% ($1.00-$1.60), depending on the anti-HCV prevalence of the population being tested. For hemodialysis patients, the cost increases from a minimum of 16% ($1.00) to a maximum of 38% ($2.44). Performing reflex NATs on all screening-test-positive samples with average s/co ratios <3.8, followed by RIBA on those that are NAT-negative (scheme 2), increases the cost of testing per sample for immunocompetent populations from a minimum of 9%-21% ($0.73-$1.14) to a maximum of 37%-85% ($2.88-$4.54), compared with performing only the screening test. For hemodialysis patients, the cost increases from a minimum of 27% ($1.73) to a maximum of 109% ($6.88). The higher incremental costs of scheme 2 compared with scheme 1 are because virtually all the screening-test-positive samples with s/co ratios <3.8 test HCV ribonucleic acid (RNA)-negative and require follow-up testing with RIBA to verify anti-HCV status.

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Rationale

Testing for hepatitis C virus (HCV) infection by using anti-HCV is performed for 1) clinical diagnosis of patients with signs or symptoms of liver disease; 2) management of occupational and perinatal exposures; and 3) screening asymptomatic persons to identify HCV-infected persons who should receive counseling and medical evaluation. Anti-HCV test results also are used for public health surveillance to monitor incidence and prevalence and to target and evaluate HCV prevention efforts.

Anti-HCV testing is performed in multiple settings, including hospitals and other health-care facilities, physicians' offices, health department clinics, HIV or other freestanding counseling and testing sites, employment sites, and health fairs. The interpretation of anti-HCV screening-test-positive results in these settings can be problematic. Clinical information related to the persons tested often is lacking, and even persons with risk factors for HCV infection might be at sufficiently low enough risk for infection that their screening test results could be falsely positive (e.g., health-care professionals are at occupational risk for HCV infection, but their overall prevalence of infection is low). (Alter, 2002) Without knowledge of the origin of the test sample or clinical information related to the person being tested, the accuracy of a screening-test-positive result for any given specimen cannot be determined.

However, despite previous recommendations for reflex supplemental testing of all anti-HCV screening-test-positive results (CDC, 1998), the majority of laboratories report positive anti-HCV results based only on a positive screening assay. To facilitate and improve the practice of reflex supplemental testing, the recommended anti-HCV testing algorithm has been expanded to include an option for more specific testing based on the signal to cut-off (s/co) ratios of screening-test-positive results that can be implemented without substantial increases in testing costs.

Implementation of these recommendations will provide more reliable results for physicians and their patients, so that further counseling and clinical evaluation are limited to those confirmed to have been infected with HCV. This is critical for persons being tested for HCV infection for the first time, for persons being tested in nonclinical settings, and for those being tested to determine the need for postexposure follow-up. Implementation of these recommendations also will improve public health surveillance systems for monitoring the effect of HCV prevention and control activities.

Laboratory Algorithm for Anti-HCV Testing and Result Reporting

All laboratories that provide anti-HCV testing should perform initial screening with a Food and Drug Administration (FDA)-licensed or approved anti-HCV test according to the manufacturer's labeling.

- Screening-test-negative (i.e., nonreactive) samples require no further testing and can be reported as anti-HCV-negative.
- Screening-test-positive samples require reflex serologic or nucleic acid supplemental testing according to the testing algorithm. Laboratorians can choose to perform reflex supplemental testing 1) based on screening-test-positive s/co ratios, or 2) on all specimens with screening-test-positive results.
    - For screening-test-positive samples that require reflex supplemental testing (according to the testing option chosen), the anti-HCV result should not be reported until the results from the additional tests are available.

Reflex Supplemental Testing Based on Screening-Test-Positive Signal to Cut-Off (S/Co) Ratios

- Laboratories should use only screening tests that have been evaluated for this purpose* and for which high s/co ratios have been demonstrated to predict a supplemental-test-positive $\geq$95% of the time among all populations tested.
- Screening-test-positive samples with high s/co ratios can be reported as anti-HCV-positive without supplemental testing.
- A comment should accompany the report indicating that supplemental serologic testing was not performed, and it should include a statement that samples with high s/co ratios usually ($\geq$95%) confirm positive, but <5 of every 100 samples with these results might be false-positives. The ordering physician also should be informed that more specific testing can be requested, if indicated.
- Screening-test-positive samples with low s/co ratios should have reflex supplemental testing performed, preferably recombinant immunoblot assay (RIBA) (see Figure 4 in the original guideline document).

*Note: Data are available from three screening assays. For the two enzyme immunoassays (HCV EIA 2.0 or HCV Version 3.0 ELISA), high s/co ratios are defined as screening-test-positive results with average s/co ratios $\geq$3.8, and low s/co ratios as screening-test-positive results with average s/co ratios <3.8. For chemiluminescence immunoassay (VITROS Anti-HCV), high s/co ratios are defined as screening-test-positive results with s/co ratios $\geq$8, and low s/co ratios as screening-test-positive results with s/co ratios <8.

Reflex Supplemental Testing on All Specimens with Screening-Test-Positive Results

- RIBA only
- Nucleic acid test (NAT), followed by RIBA for specimens with NAT-negative results

Considerations When Choosing a Reflex Supplemental Testing Option

Serologic Supplemental Testing

- RIBA can be performed on the same sample collected for the screening test.
- RIBA is the most cost-effective supplemental test for verifying anti-HCV status for screening-test-positive samples with low s/co ratios.

- The RIBA result is used to report the anti-HCV result.

Nucleic Acid Supplemental Testing

- NATs can be performed in laboratories that have facilities specifically designed for that purpose.
- Serum or plasma samples must be collected, processed, and stored in a manner suitable for NATs to minimize false-negative results (Davis et al., 1994).
    - Blood should be collected in sterile collection tubes with no additives or in sterile tubes by using ethylenediaminetetraacetic acid (EDTA).
    - Serum or EDTA plasma must be separated from cellular components within 2-6 hours after collection.
    - Storage of serum or EDTA plasma at 2 degrees C to 5 degrees C is limited to 72 hours; for longer storage, freezing at -20 degrees C or -70 degrees C is recommended. If shipping is required, frozen samples should be protected from thawing.
    - Samples collected for serologic testing can be used only if the previous conditions are met.
- Because of assay variability, rigorous quality assurance and control should be standards of practice in clinical laboratories performing this assay; proficiency testing is recommended, including monitoring for false-positive results.
    - Technician proficiency can vary and increases in direct relation to experience.
    - Intra-assay contamination can occur, including aerosolization, splashing, and carry-over.
- If the HCV ribonucleic acid (RNA) result is positive, the presence of active HCV infection can be reported as well as a positive anti-HCV result.
- An HCV RNA-negative result requires that RIBA be performed and the RIBA result used to report the anti-HCV result.

Other Reflex Supplemental Testing Options

Certain laboratories might choose to modify the recommended supplemental testing options to provide additional information before reporting results. One such modification might include reflex NAT of screening-test-positive results with high s/co ratios, which might be of interest to hospital-based laboratories that usually test specimens from patients being evaluated for liver disease. If the NAT result is positive, the presence of active HCV infection can be reported as well as a positive anti-HCV result. However, if the NAT result is negative, reflex RIBA testing still is required before reporting the results to verify the anti-HCV status. Certain specimens will test RIBA-positive, indicating that the person should receive further evaluation, including repeat testing for HCV RNA (see Interpretation of Anti-HCV Test Results).

CLINICAL ALGORITHM(S)

An algorithm is provided for antibody to hepatitis C virus testing and reporting results.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

REFERENCES SUPPORTING THE RECOMMENDATIONS

References open in a new window

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The guidelines were developed on the basis of available knowledge of the Centers for Disease Control and Prevention (CDC) staff in consultation with representatives from the Food and Drug Administration and public health, hospital, and independent laboratories. Additional information needed to develop the guidelines was generated through serologic and nucleic acid testing.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Verifying the presence of anti-hepatitis C virus (HCV) minimizes unnecessary medical visits and psychological harm for persons who test falsely positive by screening assays and ensures that counseling, medical referral, and evaluation are targeted for patients serologically confirmed as having been infected with HCV.
- Use of signal to cut-off (s/co) ratios minimizes the amount of supplemental testing that needs to be performed while improving the reliability of reported test results.
- The specificity of the HCV EIA 2.0 and HCV Version 3.0 ELISA is $\geq$99%.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Use of trade names and commercial sources is for identification only and does not imply endorsement by the United States Department of Health and Human Services.
- The guidelines are not intended to be used for blood, plasma, organ, tissue, or other donor screening or notification as provided for under Food and Drug Administration (FDA) guidance or applicable regulations. They also are not intended to change the manufacturer´s labeling for performing a specific test.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

To implement these recommendations for anti-hepatitis C virus (HCV) testing and result reporting, laboratories should review their present testing and reporting methods and determine how those should be modified. This process should include:

- determining which reflex supplemental testing option will be implemented
- revising standard operating procedures to include the reflex testing option selected, the procedure for reporting results, and the interpretation of those results (refer to Table 3 in the original guideline document)
- educating the laboratory staff, physicians, and other end-users
- modifying the laboratory requisition form, if necessary. For purposes of reimbursement, the circumstances under which reflex supplemental testing will be performed might need to be included on the form to serve as documentation that the additional tests were ordered

Laboratories that select a reflex supplemental testing option based on screening-test-positive signal to cut-off (s/co) ratios need to ensure that their analyzers generate optical density (OD) values in a range sufficient to calculate s/co ratios at or above the value defined as a high s/co ratio for the screening test being used. The s/co ratio is calculated by dividing the OD value of the sample being tested by the OD value of the assay cut-off for that run. Depending on the type of equipment in the laboratory, the calculation of s/co ratios might be automatically performed by the analyzer or require that the technician manually perform the calculation.

For screening tests that require only one reactive result to indicate a screening-test-positive result (e.g., VITROS Anti-HCV), the s/co ratio of the reactive result is used to determine the next step in the algorithm (i.e., reporting the result or reflex supplemental testing). For screening tests that require repeating initially reactive results in duplicate (e.g., HCV enzyme immunoassay (EIA) 2.0 and HCV Version 3.0 ELISA), the s/co ratio of each of the duplicate results is calculated. The average of the s/co ratios of the reactive results is used to determine the next step in the algorithm. If all three results are reactive for the sample, the average s/co ratio can be determined either by averaging the ratios of all three or by averaging only the ratios of the two duplicate reactive results. If only one of the duplicate results is reactive, the average s/co ratio is determined by averaging the ratios from the initial reactive result and the one duplicate reactive result.

For those screening-test-positive samples that undergo reflex supplemental testing (according to the testing option chosen), the screening test anti-HCV results should not be reported before the results from the additional testing are available. If necessary, an interim report can be issued indicating that the result is pending. This procedure should be followed even if the laboratory does not perform the supplemental testing in-house, but sends the sample to another reference laboratory for such testing. After the results are received from the reference laboratory, the final results can be reported on the basis of the testing performed by both laboratories.

The reported results should be accompanied by interpretive comments as determined by each laboratory. The content of these comments will vary on the basis of type of supplemental testing option selected by the laboratory. These comments are critical if screening-test-positive results are reported as anti-HCV-

positive on the basis of high s/co ratios, because the health-care professional or other person interpreting the results needs to understand the limitations of the testing option used.

Before implementation, the laboratory staff should be educated regarding new methods of testing, calculating, and reporting final results for the selected testing option. Laboratories also should inform and educate all customers regarding the planned changes and what effects they will have on test results generated. This information should be disseminated as widely as possible (e.g., by laboratory bulletins, letters, Internet, or continuing education programs).

Depending on the setting, reimbursement of clinical laboratory tests used for reflex supplemental testing might depend on documentation that the physician ordered the tests. This documentation can be achieved through a printed requisition form that clearly identifies for anti-HCV the specified level of results of the screening test that will trigger additional supplemental testing and what type(s) of supplemental testing will be performed. In addition, each of the supplemental tests (e.g., recombinant immunoblot assay [RIBA] or nucleic acid test [NAT]) that are offered by the laboratory should be listed separately, because physicians should be able to order these as they deem necessary for further medical evaluation.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Alter MJ, Kuhnert WL, Finelli L. Guidelines for laboratory testing and result reporting of antibody to hepatitis C virus. Centers for Disease Control and Prevention. MMWR Recomm Rep 2003 Feb 7;52(RR-3):1-13, 15. [30 references] PubMed

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Feb 7

GUIDELINE DEVELOPER(S)

Centers for Disease Control and Prevention - Federal Government Agency [U.S.]

SOURCE(S) OF FUNDING

United States Government

GUIDELINE COMMITTEE

Laboratory Testing and Result Reporting of Antibody to Hepatitis C Virus Working Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Report Prepared by: Miriam J. Alter, Ph.D.; Wendi L. Kuhnert, Ph.D.; Lyn Finelli, Dr.P.H. (Division of Viral Hepatitis, National Center for Infectious Diseases)

Working Group Members: Miriam J. Alter, Ph.D., Wendi L. Kuhnert, Ph.D., Lyn Finelli, Dr.P.H., Division of Viral Hepatitis, National Center for Infectious Diseases, CDC; William Schalla, M.S., Ana Stankovic, M.D., Ph.D., Robert Martin, Dr.P.H., Division of Laboratory Systems, Public Health Program Practice Office, CDC; Robin Biswas, M.D., Brian Harvey, M.D., Ph.D., Food and Drug Administration, Bethesda, Maryland; John Bryan, M.D., American Society for Clinical Pathology, Chicago, Illinois; D. Robert Dufour, M.D., National Academy of Clinical Biochemistry, Washington, D.C.; Mark Jandreski, Ph.D., American Association for Clinical Chemistry, Washington, D.C.; Amy Leber, Ph.D., American Clinical Laboratory Association, Washington, D.C.; Frederick Nolte, Ph.D., Emory University School of Medicine, Atlanta, Georgia; Robin Stombler, American Society for Clinical Pathology, Washington, D.C.; David Sundwall, M.D., American Clinical Laboratory Association, Washington, D.C.; James Versalovic, M.D., Ph.D., College of American Pathologists, Northfield, Illinois; Judith Wethers, M.S., New York State Public Health Laboratory, Albany, New York; Barbara Werner, Ph.D., Association of Public Health Laboratories, Washington, D.C.; and Susanne Zanto, Association of Public Health Laboratories, Washington, D.C.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

The preparers of this report have signed a conflict of interest disclosure form that verifies no conflict of interest.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available from the Centers for Disease Control and Prevention (CDC) Web site:

- HTML Format

- Portable Document Format (PDF)

Print copies: Available from the Centers for Disease Control and Prevention, MMWR, Atlanta, GA 30333. Additional copies can be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402-9325; (202) 783-3238.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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