IVD

Instructions for use (English)

1 Intended purpose

The *recom*CLIA HEV IgM is a semi-quantitative *in vitro* chemiluminescent immunoassay (CLIA) for the detection of IgM antibodies against Hepatitis E Virus (HEV) in human serum and plasma (EDTA, heparin, citrate, CPD) from symptomatic patients or individuals suspected of infection with HEV.
The assay is used for screening and aid in the diagnosis of infection with HEV and the associated diseases, in combination with other laboratory and clinical findings. This assay is not intended to be used for screening in donors and recipients to detect the presence of IgM antibodies against HEV in blood, blood components, cells, tissues, organs, or any of their derivatives in order to assess their suitability for transfusion, transplantation, or cell administration.

The *recom*CLIA HEV IgM can only be performed as an automated assay using KleeYa® Instrument, STRATEC SE, by trained professional users in a suitable laboratory.

2 Summary and explanation

The Hepatitis E Virus is one of the most common viral causes of acute hepatitis worldwide. Therefore, IgG and IgM HEV antibody detection using the *recom*CLIA HEV IgG, IgM can support correct diagnosis, reduce complications and unnecessary laboratory testing, and allow the physician to determine appropriate treatment. An HEV infection may present as clinically inapparent to fulminant.

There are four predominant human-pathogenic genotypes (1-4), which differ in their geographical distribution, modes of transmission and potential complications. HEV genotype 1 and 2 infections occur primarily in developing countries where transmission predominantly occurs through the faecal-oral route via contaminated drinking water. HEV genotypes 3 and 4, which are widespread in industrialised countries, are predominantly transmitted through the consumption of inadequately cooked pork. In Europe, most cases are caused by HEV genotype 3 and are often asymptomatic. The human-pathogenic HEV genotypes show serological cross-reactivity and are classified under a single serotype.

3 Test principle

Magnetic microparticles are coated with highly purified recombinant ORF2C HEV antigen.

1. The antigen particles are incubated with the diluted serum/plasma where specific antibodies attach to the pathogen antigens on the microparticles.
2. Unbound antibodies are then washed away.
3. In a second step, the microparticles are incubated with anti-human immunoglobulin antibodies (IgM), which are conjugated to a chemiluminescent tracer (acridinium ester).
4. Unbound conjugate antibodies are then washed away.
5. After addition of hydrogen peroxide and sodium hydroxide (KleeYa® TRIGGER SOLUTION (Trigger Solution 1 and Trigger Solution 2)), the acridinium ester conjugate is activated and undergoes chemiluminescence, thereby emitting light quanta.
6. The intensity of the chemiluminescent reaction is measured in relative light units (RLU) and is proportional to the concentration of specific antibodies in the sample.
7. The measured RLU are converted to cut-off index (COI) values using a batch- and device-specific calibration line, which must be recalibrated by cut-off control IgM prior to the measurement of sample material (for details refer to chapter 9.1.1 “Validation criteria”).

4 Reagents

4.1 Package contents

The reagents in one package are sufficient for 100 tests.

RGT CART	**Reagent cartridge,** ready-to-use contains the following:
BEADMIX	**2.5 ml magnetic particles** suspension ready-to-use coated with antigen contains preservative: Methylisothiazolinone (MIT) (0.01%) contains ingredient of animal origin: Bovine serum albumin (BSA) (0.5%)
DILUBUF	**2 x 10 ml *recom*CLIA Dilution Buffer A** ready-to-use contains preservative: MIT (0.01%) contains ingredient of animal origin: BSA (1.0%)
CONJ IgM	**2 x 10 ml anti-human IgM conjugate** ready-to-use solution containing mouse immunoglobulin to human IgM antibodies, labelled with acridinium ester contains preservative: MIT (0.01%) contains ingredient of animal origin: BSA (1.0%)
CONTROL ± IgM	**2 x 400 µl cut-off control IgM (white cap)** **one vial is sufficient to perform 15 recalibrations in double testing (30 reactions in total)** ready-to-use human origin, anti-HIV 1/2, anti-HCV and HBs Ag negative contains preservative: MIT (0.1%) contains ingredient of animal origin: BSA (0.05%)
INSTRU	**1 instructions for use**

4.2 Additionally required reagents, materials and equipment

- Fully automated KleeYa® Instrument, STRATEC SE (MIKROGEN article no. 31349)
- KleeYa® TRIGGER SOLUTION (Trigger Solution 1 and Trigger Solution 2), Diatron MI Plc. (MIKROGEN article no. 31334)
- 5x TBS Wash Buffer, Diatron MI Plc. (MIKROGEN article no. 31335)
- Stackable Cuvette, 1 ml, STRATEC Consumables GmbH (MIKROGEN article no. 31336)
- Disposable Anchor® Tips, 300 µl, STRATEC Consumables GmbH (MIKROGEN article no. 31337)
- *recom*CLIA Sample Diluent A, MIKROGEN (article no. 10120)
- KleeYa® Maintenance Cartridge, Diatron MI Plc. (MIKROGEN article no. 31354)
- Deionised water (high quality)
- Single-use protective gloves, other personal protective equipment
- Waste container for bio-hazardous material
- Solid waste bag

Optional materials:
*recom*CLIA Control Set HEV IgM, MIKROGEN (article no. 75003)

MIKROGEN recommends processing the product line *recom*CLIA with a defoamer (for details refer to chapter 7.4 “Use of defoamer”):
Defoamer “Entschäumer“, KIEHL Group (MIKROGEN article no. 31433)

For more information please contact the Technical Support of MIKROGEN.

5 Shelf life and handling

- Store reagents at +2 °C to +8 °C before and after use, **do not freeze**.
- Shelf life:

Shelf life of kit	
Unopened at +2 °C to +8 °C	Until the stated expiry date
In-use stability* +2 °C to +8 °C	3 months
On-board stability of reagent cartridge +10 °C to +12 °C	28 days

* In-use stability starts after first use of the reagent cartridge.

After the expiry date of the kit, the quality can no longer be guaranteed.

- The storage conditions and stability of working solutions are described in chapter 7.2 “Preparation of solutions”.
- The components *recom*CLIA Dilution Buffer A, conjugate and magnetic particles must remain in the reagent cartridge and must not be removed.

- The wash buffer (5x TBS Wash Buffer) and KleeYa® TRIGGER SOLUTION (Trigger Solution 1 and Trigger Solution 2) are universal for all *recom*CLIA kits and can be used across the full range of parameters and batches. The shelf life of these components must be adhered to.
- The *recom*CLIA Sample Diluent A can be used batch-independently in combination with the corresponding *recom*CLIA test kits. The same *recom*CLIA Sample Diluent A reagent cartridge allows parallel sample processing for multiple test kits. The shelf life of *recom*CLIA Sample Diluent A must be adhered to.
- The cut-off control IgM is batch-dependent and can only be used with the respective assay and batch.
- The cut-off control IgM should be prewarmed to room temperature (18 °C to 25 °C) for 30 minutes before performing the recalibration.
- The cut-off control IgM is not intended to be stored within the KleeYa® Instrument. Return the cut-off control IgM to +2 °C to +8 °C immediately after successful recalibration.
- The test must be carried out by a trained and authorised professional user.
- In the event of significant changes to the product or modifications to its use by the user, the application may no longer align with the intended purpose outlined by MIKROGEN.

6 Warnings and safety precautions

- For *in vitro* diagnostic use only.
- All blood products must be treated as potentially infectious.
- The microparticles must be considered potentially infectious after addition of patient or control/calibrator specimens and must be treated accordingly.
- Suitable disposable gloves must be worn throughout the entire test procedure.
- For cut-off control IgM production, donor blood free of HIV 1/2 antibodies, HCV antibodies, and free of HBs antigen is used. The product must be handled with the same precaution as a patient sample, as infectious risk cannot be excluded with certainty.
- Safety notes for reagents containing hazardous substances:

RGT CART | CONTROL ± | IgM	
	Contains ingredient of animal origin
	H317: May cause an allergic skin reaction

CONTROL ± | IgM	
	Contains human blood or plasma derivatives

  Further information can be found in the respective safety data sheets available from MIKROGEN.
  Due to space constraints, the hazard symbols of individual components cannot always be affixed to their corresponding labels. For the hazard symbols of these components, please refer to the nearest larger outer packaging or their corresponding instructions for use.
- All fluids for disposal must be collected. All collecting containers must contain suitable disinfectants for the inactivation of human pathogens. All reagents and materials contaminated with potentially infectious samples must be treated with suitable disinfectants or disposed of in accordance with applicable hygiene regulations. The concentrations and exposure times specified by the manufacturer must be strictly followed.
- All waste must be disposed of in accordance with local guidelines.
- The reagents must not be substituted or mixed with those from other manufacturers.
- The entire instructions for use document must be read before performing the test. Follow the instructions exactly as described. Any deviation from the specified test protocol may lead to incorrect results.
- Any serious incident that occurs in relation to the device must be reported to the manufacturer and the competent authority of the member state in which the user and/or the patient is established.
- The reagents contain the antimicrobial agent MIT (methylisothiazolinone). Avoid contact with the skin or mucous membranes.

7 Sampling and preparation

7.1 Sample material

The samples can be serum or plasma (EDTA, citrate, heparin, CPD). The blood collection should be carried out according to the standard technique of the laboratory or clinician. Serum or plasma must be separated from the blood clot as soon as possible after blood sampling to avoid haemolysis. Avoid microbial contamination of the samples. Insoluble substances must be removed from the sample prior to incubation. The use of heat-inactivated, icteric, haemolytic, lipemic or turbid samples is not recommended.
Package, label and transport the specimen in accordance with local and international regulations for the transport of clinical specimens and aetiological agents.
Caution!
In the event of delayed testing, samples may be stored for up to 2 weeks at +2 °C to +8 °C. Prolonged storage of samples is possible at −20 °C or below. Repeated freezing and thawing of samples is not recommended due to the risk of inaccurate results. Avoid more than 3 cycles of freezing and thawing.

7.2 Preparation of solutions

Dilute the wash buffer (5x TBS Wash Buffer) 1:5 (1 volume unit of the solution with 4 volume units of deionised water).
For example, 2 L of 5x TBS Wash Buffer + 8 L of deionised water.

After completion of the wash buffer preparation, the cap must be placed lightly on the container to allow proper degassing of the wash buffer solution. Wait 2 hours for the microbubbles to disappear from the buffer before use. The diluted wash buffer is stable for one month (on-board stability).

No further preparations of any other solutions are necessary.
All reagents in the cartridge are ready-to-use, do not dilute further!
The cut-off control IgM is ready-to-use, do not dilute further!

7.3 Preparation and maintenance of the KleeYa® Instrument

- Load and prime the KleeYa® TRIGGER SOLUTION (Trigger Solution 1 and Trigger Solution 2).
- Ensure that the respective assays are loaded into the KleeYa® Software.
- Check disposables and refill if necessary.
- Perform maintenance tasks.

For further information please refer to the manual of the KleeYa® Instrument.

7.4 Use of defoamer

To avoid foam formation in the liquid waste container during high throughput runs, it is recommended to use the defoamer, provided by the KIEHL Group called “Entschäumer”.

Proceed as follows:
- Empty the liquid waste container.
- Add 20 ml of “KIEHL Entschäumer” to the empty container.
- Place container into instrument and run tests.

For more information regarding assays for analysis, please contact the Technical Support of MIKROGEN.

8 Test procedure

No.	Implementation	Note
1	<u>Load reagent cartridge</u> Place the reagent cartridge in the reagent rack and insert it into the KleeYa® Instrument. Also place the *recom*CLIA Sample Diluent A cartridge in the rack and insert it into the KleeYa® Instrument.	The reagent cartridge will be identified automatically by the RFID-tag. The reagent cartridge is ready for use after approx. 5 minutes which allows the magnetic particles to be mixed thoroughly.
2	<u>Preparing samples, cut-off control IgM and/or other controls</u> Prewarm the cut-off control IgM to room temperature (see chapter 5 for details). Place samples and, if required, cut-off control, and/or controls in the sample rack and insert them into the KleeYa® Instrument.	Check for correct orientation of the sample barcode to allow automated sample identification. If samples do not carry a barcode, manual assignment of sample identifiers in the software is possible. Cut-off control IgM is automatically assigned based on its barcode.

		Required sample volume: 22 µl Exact dead volumes depend on the used sample tubes and vary from 50–175 µl; for further information please contact the Technical Support of MIKROGEN.
3	Perform recalibration For correct evaluation of test results, recalibration is needed. The assignment of the respective assay to the cut-off control IgM is done automatically.	Recalibration must be performed before the first measurement of the day and is valid for 24 hours. Cut-off control IgM is automatically prioritised during sample processing.
4	Perform analysis Assign all samples to be tested to the respective assay. Press the start button.	After the test is started, all assay steps are performed automatically. The result of the first test is available after approx. 30 minutes.

For further information please refer to the manual of the KleeYa® Instrument.

9 Results

9.1 Validation – Quality Control

9.1.1 *Validation criteria*
*recom*CLIA HEV IgM results are valid if the recalibration is accepted, as indicated within the KleeYa® Software.
Prior measurement of the cut-off control IgM (at the beginning of the test series of *recom*CLIA HEV IgM as double determination and mean value calculation) allows an adjustment of the predefined calibration by the determined RLUs.
Recalibration by use of cut-off control IgM takes place before the first measurement of *recom*CLIA HEV IgM of the day and is valid for 24 hours. If the cut-off control IgM result is outside the acceptance range, re-run the recalibration. If the cut-off control IgM remains outside the acceptance range, please contact the Technical Support of MIKROGEN.

9.1.2 *Laboratory internal reproducibility (optional)*
If required, the reproducibility of results can be determined for internal laboratory quality control purposes.
In this case, the *recom*CLIA Control Set HEV IgM (article no. 75003) can be used. The results should be within the recommended target value range given in the analysis certificate or on the label of the quality control. The *recom*CLIA Control Set HEV IgM is not mandatory for *recom*CLIA HEV IgM.
For further information please refer to the respective instructions for use.

9.2 Semiquantitative analysis

HEV IgM antibody concentrations are approximated by **cut-off index (COI) values.** According to index values the test results are qualified.

Negative	< 1.0 COI
Borderline	≥ 1.0 COI to < 1.2 COI
Positive	≥ 1.2 COI

Samples yielding a borderline test result should be retested. If they remain borderline upon retesting, it is recommended to analyse a follow-up sample after 1 to 2 weeks.

The measuring range of the assay is defined by the Limit of Quantitation (LoQ) and upper Limit of Quantitation (ULoQ) and ranges from 0.44 COI to 13.0 COI. If a measurement value exceeds the measurement range, the result label is “over”.

9.3 Interpretation of test results

IgG	IgM	Test interpretation
Negative	Negative	No indication of HEV infection. If clinical suspicion persists, a follow-up should be performed after approximately 1 to 2 weeks.
Negative	Positive	IgM antibodies against HEV present. Possible early stage of HEV infection. Direct pathogen detection or follow-up after approximately 1 to 2 weeks.
Positive	Positive	Indication of an acute HEV infection.
Positive	Negative	IgG antibodies against HEV present. There may have been a recent infection or a past infection.

10 Limits of the method, restrictions

- Serological test results must always be seen in the context of the clinical picture of the patient. The therapeutic consequences of the serological findings must always be taken in context with the clinical data.
- HEV serological tests are not intended for use in asymptomatic individuals, as they have not been validated for this indication and may yield results of limited clinical relevance.
- If test results are unclear or inconclusive, repeat testing over the course of the infection is recommended. Additionally, laboratory findings, clinical symptoms and patient history should all be considered to accurately diagnose HEV infection and determine the stage of disease.
- A negative test result for *recom*CLIA HEV cannot exclude an infection with HEV. In the early phase of the infection, antibodies may not be present or not present in a detectable quantity. With persistent clinical suspicion of an HEV infection and negative and/or inconclusive serological results, further sampling and testing must be performed after approximately one to two weeks.
- A positive result in *recom*CLIA HEV IgG indicates a previous or an active primary infection. An additional IgM test result is required to complete the serological diagnosis.
- An isolated positive test result with *recom*CLIA HEV IgM may point to an acute HEV infection. Further sampling and testing must be performed after two to three weeks. IgG titres typically appear after a short delay.
- Through selective use of the recombinant HEV antigen, cross-reactivity is minimised; particularly for antibodies of other hepatic viruses (e.g. Hepatitis A, B, C, EBV).
- In a considerable proportion of immunosuppressed patients (transplant and hematologic patients) with persistent HEV infection, both IgG and IgM antibody responses may show prolonged absence, e.g. for years. Therefore, PCR is the method of choice for organ and hematologic transplant recipients.
- No interference from triglyceride (93.75–1500 mg/dL), hemolysate (62.5–1000 mg/dL) or bilirubin (0.2–40 mg/dL) on *recom*CLIA HEV IgM is detected.
- For samples with protein concentrations (HSA and γ-globulins) exceeding 6000 mg/dL, interference with test reactivity cannot be excluded; therefore, such samples should not be used.

11 Performance characteristics

For the purpose of the following evaluations, all borderline test results were evaluated as positive.

11.1 Analytical performance characteristics

11.1.1 *Analytical sensitivity*

Limit of Blank (LoB), Limit of Detection (LoD) and Limit of Quantitation (LoQ)
The Limit of Blank (LoB) and Limit of Detection (LoD) describe the lowest concentration of a measurand that can be reliably measured using an analytical procedure. The LoB is the highest expected analyte concentration when replicates of a blank sample are tested. The LoD is the lowest analyte concentration that is likely to be reliably distinguished from the LoB and at which detection is deemed feasible.
Limit of Quantitation (LoQ) is the smallest amount of an analyte in a material that can be quantitively determined with state of the art accuracy (as total error or as independent requirements for bias and precision under stated experimental conditions). The data used to assess inter-lot variability was also used for the determination of LoB, LoD and LoQ according to the CLSI (Clinical and Laboratory Standards Institute) guideline EP17-A2.

Analytical sensitivity	***recom*CLIA HEV IgM**
Limit of Blank (LoB)	0.05 COI
Limit of Detection (LoD)	0.16 COI
Limit of Quantitation (LoQ)	0.44 COI

11.1.2 *Analytical specificity*
The analytical specificity refers to the test’s capacity to accurately measure the analyte in the presence of potential interference factors (exogenous and endogenous) in the sample matrix or cross-reactivity with potentially interfering antibodies.

11.1.2.1 *Exogenous interferences*
A control study with serum-plasma quintets – comprising serum, heparin-, CPD-, sodium citrate- and EDTA-plasma samples collected at the

same time point – showed that the presence of these anticoagulants does not affect test efficiency. Furthermore, no interference was observed in samples of patients with a history of alcohol abuse and drug use (Clozapin).

11.1.2.2 *Endogenous interferences*
To determine the influence of potentially endogenous interfering substances on test performance, interference testing was conducted according to the CLSI guideline EP07-A2.

No impact on the test efficiency was observed for the following concentration ranges:
- Triglyceride-rich lipoproteins: 93.75–1500 mg/dL
- Hemolysate: 62.5–1000 mg/dL
- Conjugated bilirubin: 0.2–40 mg/dL
- Unconjugated bilirubin: 0.6–40 mg/dL
- Protein (HSA and γ-globulins): 1500–6000 mg/dL. 12000 mg/dL HSA impairs the test performance.

No interference from triglyceride (93.75–1500 mg/dL), hemolysate (62.5–1000 mg/dL), bilirubin (0.2–40 mg/dL) or protein (1500–6000 mg/dL HSA and γ-globulins) on *recom*CLIA HEV IgM is observed.

A negative influence on test performance due to protein (HSA and γ-globulins) concentrations > 6000 mg/dL in the sample material cannot be excluded. Therefore, the use of samples with protein concentrations > 6000 mg/dL is not recommended.

11.1.2.3 *Cross-reactions*
The potential interference from antibodies against other organisms that may cause similar clinical symptoms (e.g. HAV, EBV, HIV, HCV, Parvovirus B19) as well as from conditions associated with atypical immune activity (e.g. antinuclear autoimmune antibodies, pregnancy, increased levels of rheumatoid factor, hypergammaglobulinemia) were tested. No cross-reactions were observed.

Positivity rate	***recom*CLIA HEV IgM**
Diseases with similar clinical picture (n = 172)	0.9%
Conditions with atypical activity of the immune system (n = 180)	2.2%

11.1.3 *Accuracy of measurement (reproducibility)*

Precision
Intra-assay, inter-assay and inter-lot variability were determined. The coefficient of variation was calculated based on the resulting COI for samples with a borderline or positive reactivity finding.

Precision	***recom*CLIA HEV IgM**
Intra-assay variability	< 8.6%
Inter-assay variability	< 10.0%
Inter-lot variability	< 11.8%

11.1.4 *Measuring range of the assay*

11.1.4.1 *Linearity*
Test linearity was determined to lie within the range of 0.6 COI to 16 COI ($R^2 > 0.95$).

11.1.4.2 *Metrological traceability*
The measurement units COI (cut-off index values) are arbitrary units. At MIKROGEN, method references – including control specifications – are internally defined as target values with specified tolerance ranges. These are verified for each batch using defined serum panels.

The specifications for the measuring ranges are outlined in chapter 9.2 “Semiquantitative analysis”.

11.2 Clinical performance characteristics

11.2.1 *Diagnostic sensitivity and specificity*
Predefined samples were analysed to determine diagnostic sensitivity and specificity. The 95% confidence interval was calculated using the Wilson Score Interval.

11.2.1.1 *Diagnostic sensitivity*

Suspected acute HEV infection (n = 79)*	***recom*CLIA HEV IgM**
Positive	76
Borderline	1
Negative	2
Diagnostic sensitivity (95% confidence interval)	**97.5% (91.2%–99.6%)**

* Predefined samples, reactive with two commercial anti-HEV IgM assays

11.2.1.2 *Diagnostic specificity*

Routine acute hepatitis samples (n = 155)*	***recom*CLIA HEV IgM**
Positive	0
Negative	155
Relative diagnostic specificity (95% confidence interval)	**100% (97.6%–100%)**

* Samples predefined as negatives by concordant negative results of two commercial anti-HEV IgM assays

Blood donor samples (n = 200)*	***recom*CLIA HEV IgM**
Positive	3
Borderline	1
Negative	196
Relative diagnostic specificity (95% confidence interval)	**98.0% (95.0%–99.2%)**

* Samples predefined as negatives by concordant negative results of three commercial anti-HEV IgM assays

11.2.2 *Expected values*
Expected values were determined during test evaluation using samples from healthy individuals, represented by German blood donors, and from affected patients, represented by a presumed HEV-positive cohort in routine clinical testing.

***recom*CLIA HEV IgM**	**Normal population (blood donors, n = 200)**	**Affected population (routine panel, n = 167)**
Positive	3	8
Borderline	1	1
Negative	196	158
Prevalence	**2.0%**	**5.7%**

Expected values may vary by region and panel composition.

11.2.3 *Predictive values*
The positive predictive value (PPV) and negative predictive value (NPV) indicate the proportion of positive and negative test results that are true positives and true negatives, respectively. The PPV indicates the probability that a positive test result truly identifies the presence of the condition, while the NPV indicates the probability that a negative test result truly excludes the condition. PPV and NPV were determined using 167 consecutive samples from acute hepatitis routine testing. Samples, classified as reactive or nonreactive based on a commonly used HEV IgM assay, were classified as true positive or true negative, respectively.

Study predictive value	***recom*CLIA HEV IgM**
Positive predictive value (PPV)	100%
Negative predictive value (NPV)	98.7%

11.2.4 *Likelihood ratio*
Likelihood ratios are used to assess the value of performing a diagnostic test. The positive likelihood ratio (LR+) is defined as the ratio of the true positive rate to the false positive rate. It indicates the extent to which a positive test result is more likely in a person with the disease compared to one without. Therefore, this statistical measure provides clinical information about an individual. Conversely, the negative likelihood ratio (LR–) is the ratio of the false negative rate to the true negative rate. It indicates the extent to which a negative test result is more likely in a person with the disease compared to one without it.

The positive and negative likelihood ratios were determined using 167 consecutive samples from hepatitis routine testing; identical to those used in the determination of predictive values as outlined above. Samples, classified as reactive or nonreactive based on a commonly used HEV IgM assay, were classified as true positive or true negative, respectively.

Likelihood ratio	*recom*CLIA HEV IgM
Positive likelihood quotient (LR+)	> 68.2
Negative likelihood quotient (LR–)	0.18

12 Literature

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13 Explanation of symbols

	Content is sufficient for <n> applications Number of applications
RGT CART	Reagent cartridge
BEADMIX	Magnetic particles
DILUBUF	*recom*CLIA Dilution Buffer A
CONJ IgM	Anti-human IgM conjugate
CONTROL ± IgM	Cut-off control IgM
INSTRU	Instructions for use
	Follow the instructions for use
IVD	*In vitro* diagnostic medical device
REF	Order number
LOT	Batch/version number
CONT	Contents, includes
	Manufacturer
	Use by Expiry date
	Store at x °C to y °C
	Do not freeze
	Contains human blood or plasma derivatives
	Contains ingredients of animal origin
	Warning

Additions, corrections or changes to the previous version are indicated by markings in the margin.

14 Manufacturer and version data

***recom*CLIA HEV IgM**	Article no. **75005**
Instructions for use valid from	GARCHEM001EN 2025-02

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Summary of safety and performance: EUDAMED

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GARCHEM001