# corQC® EXTEND

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RunControl for Daily QC

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## Intended Use:

corQC® EXTEND is intended for use in manual test tube and automated (e.g. Galileo NEO and NEO Iris) assays for quality control of routine Rh and Kell blood grouping reagents.

## Summary of the Test:

Blood grouping antisera reagents and Reagent Red Blood Cells are extensively tested by their manufacturer during production to show that they meet or exceed minimum potency, specificity and / or reactivity standards established by the Food and Drug Administration (FDA). Subsequent to manufacture, the performance of these reagents may be altered through inappropriate shipping or storage conditions, microbial or chemical contamination. Alterations leading to reagent deterioration, i.e., loss of potency or antigen strength, manifest themselves as a weakening or loss of test reactivity. Hence, laboratories must ensure that serologic test reagents are suitably reactive each day of use.[1-3] corQC EXTEND reagents are used to evaluate the reactivity of routine blood bank reagents (e.g., Anti-D, Anti-C, Anti-c, Anti-E, Anti-e, Anti-K, Anti-CDE and the corresponding Rh control material) by automated or manual test tube methods.

## Principle of the Test:

Each vial of corQC EXTEND reagent contains a suspension of human erythrocytes of a defined Rh and K phenotypes. Selected combinations of the corQC EXTEND reagents are tested with the corresponding blood grouping reagent (i.e., Anti-D, Anti-C, Anti-c, Anti-E, Anti-e, Anti-K, Anti-CDE and the corresponding Rh control material) by automated or manual test tube methods.

If the expected combination of positive and negative reactions are obtained between the blood grouping reagent under evaluation and the corresponding corQC EXTEND reagent, the performance of the blood grouping reagent has been verified and is suitable for use. Failure to obtain the expected reactions indicates that a reagent is unsuitable for use (for example reagent deterioration or contamination), or is a sign of a technical error during manual testing or a sign the instrument has a defect which prevents tests from being performed correctly.

## Reagents:

- corQC® EXTEND Complete (Extend 1, 2, 3, 4 and Standard)
- corQC® EXTEND 1, 2 and 3
- corQC® EXTEND Standard

Each vial of corQC EXTEND contains a 2-4% suspension of group O, single donor red blood cells suspended in a buffered preservative solution containing adenosine and adenine to retard hemolysis and/or loss of antigenicity during the dating period. Chloramphenicol (0.25 mg/mL), neomycin sulfate (0.1 mg/mL), gentamycin sulfate (0.05 mg/mL) are added as preservatives.

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Each vial of corQC EXTEND has a defined antigen phenotype and is designed to be tested with selected blood grouping reagents by automated or manual test systems.

**EXTEND Standard**: 10 mL; phenotype O, D+C+c-E-e+, used to verify the reactivity of Anti-D in agglutination (and automated Weak D assays), and the specificity of Anti-c.

**EXTEND 1**: 5 mL; phenotype O, D-C+c+E-e+K-k+, used to verify the reactivity of Anti-C, Anti-c and also the component of Anti-CDE directed against the C antigen. **1** is also used to verify the specificity of Anti-K.

**EXTEND 2**: 5 mL; phenotype O, D-C-c+E+e+K-k+, used to verify the reactivity of Anti-E, Anti-e and also the component of Anti-CDE directed against the E antigen.

**EXTEND 3**: 5 mL; phenotype O, D-C-c+E-e+K+k+, used to verify the reactivity of Anti-K and the specificity of Anti-D, Anti-CDE, Anti-C, Anti-E and the corresponding Rh control material.

**EXTEND 4**: 5 mL; phenotype O, D+C-c+E+e-, used to verify the specificity of Anti-e.

## Storage:

- Store at 1–10 °C when not in use.
- Do not freeze or expose to elevated temperatures.
- Do not use beyond expiration date which is expressed as CCYY-MM-DD (year-month-day).

## Precautions and Warnings:

- For in vitro diagnostic use.
- For laboratory professional use.
- Avoid contaminating this product during use. Contamination will adversely affect product performance during its shelf life. Do not use contaminated reagents.
- Do not use leaking vials.
- Do not use unlabeled vials.
- Reagent red blood cells should not be used if the red blood cells darken, spontaneously clump, or if there is significant hemolysis. Slight hemolysis may occur with age.
- Suspend the red blood cells before use by gently inverting each vial several times.
- Magnetic stirballs are used to keep cellular reagents in suspension when used with automation. If the stirballs are not added to the red blood cell suspensions, then the suspensions will not be mixed and the results may be invalid or incorrect. Do not touch the stirballs. The stirballs must be added directly to the reagent vials using the dispenser provided. Contamination of cellular reagents can occur if the stirballs are touched.

**CAUTION**: ALL BLOOD PRODUCTS SHOULD BE TREATED AS POTENTIALLY INFECTIOUS. SOURCE MATERIAL FROM WHICH THIS PRODUCT WAS DERIVED WAS FOUND NEGATIVE WHEN TESTED IN ACCORDANCE WITH CURRENT FDA REQUIRED TESTS. NO KNOWN TEST METHODS CAN OFFER ASSURANCE THAT PRODUCTS DERIVED FROM HUMAN BLOOD WILL NOT TRANSMIT INFECTIOUS AGENTS.
Handle and dispose of the reagents as if potentially infectious.

LATEX
The packaging of this product (dropper bulbs) contains dry natural rubber.

## Procedure:

**Materials Provided:**
corQC EXTEND reagent red blood cells in dropper vials ready for use.

**Additional Materials Required for Automated Method:**
Refer to information provided in the instrument operator manual.

**Additional Materials Required for Manual Method:**

1. Phosphate-buffered (approximately 15mM) isotonic saline, pH 6.5-7.5
2. Serological centrifuge *
3. Marking pen
4. Transfer pipettes
5. 10 x 75 mm or 12 x 75 mm test tubes and a test tube rack
6. Anti-C, Anti-c, Anti-E, Anti-e, Anti-CDE, Anti-K, Anti-D and the corresponding Rh control material under evaluation

* It is the users responsibility to validate an accessory device (either listed or otherwise) for its intended use. Validation results should be maintained as part of the laboratory's records for review by regulatory agencies.

**Test Method:**
**Automated Method:**
For microplate testing with automated instrumentation, refer to instructions provided in the instrument operator manual.

**Manual Method:**

Note: The recommended method of the manufacturer for the reagent under evaluation must be followed. The method described below is intended to be used in conjunction with the specific information supplied by the manufacturer of the reagent under evaluation (e.g. the volume of reagent to be used, time and temperature and applicable test phases).

1. Before performing the quality control testing, inspect all reagents under evaluation for evidence of contamination or deterioration (i.e. marked turbidity or blood grouping reagents or hemolysis of Reagent Red Blood Cells). Allow all reagents to equilibrate to room temperature before testing. Record the lot number and expiration date of each reagent and observations.
2. Label two test tubes for each reagent to be evaluated. Tubes can be labeled as listed in the table below:

| Tube Number | Reagent |
|---|---|
| 1 | Anti-C |
| 2 | Anti-c |
| 3 | Anti-E |
| 4 | Anti-e |
| 5 | Anti-CDE |
| 6 | Anti-CDE |
| 7 | Anti-K |
| 8 | Anti-C |

| Tube Number | Reagent |
|---|---|
| 9 | Anti-c |
| 10 | Anti-E |
| 11 | Anti-e |
| 12 | Anti-CDE |
| 13 | Anti-K |
| 14 | Anti-D |
| 15 | Anti-D |
| 16 | Rh control material |

The corresponding tubes can be omitted if any reagent is not used. If any reagent is used in duplicate (e.g. where two different clones of monoclonal antisera are used), include additional appropriately labeled tubes. If one source of reagent antisera is used, the procedure is as follows:

3. Add one (1) drop of corQC EXTEND 1 to tube number 1.
4. Add one (1) drop of corQC EXTEND 1 to tube number 2.
5. Add one (1) drop of corQC EXTEND 2 to tube number 3.
6. Add one (1) drop of corQC EXTEND 2 to tube number 4.
7. Add one (1) drop of corQC EXTEND 1 to tube number 5.

Key:
Underline = Addition or significant change; ▲ = Deletion of text

8. Add one (1) drop of corQC EXTEND 2 to tube number 6.
9. Add one (1) drop of corQC EXTEND 3 to tube number 7.
10. Add one (1) drop of corQC EXTEND 3 to tube number 8.
11. Add one (1) drop of corQC EXTEND Standard to tube number 9.
12. Add one (1) drop of corQC EXTEND 3 to tube number 10.
13. Add one (1) drop of corQC EXTEND 4 to tube number 11.
14. Add one (1) drop of corQC EXTEND 3 to tube number 12.
15. Add one (1) drop of corQC EXTEND 1 to tube number 13.
16. Add one (1) drop of corQC EXTEND Standard to tube number 14.
17. Add one (1) drop of corQC EXTEND 3 to tube number 15.
18. Add one (1) drop of corQC EXTEND 3 to tube number 16.
19. Add the recommended volume of the reagent to the appropriately labeled test tubes.
20. Mix the contents of each test tube.
21. Incubate the test tubes for the recommended time and temperature.
22. Perform an antiglobulin test if required by the manufacturer's directions for use.
23. Centrifuge the test tubes and immediately after centrifugation, gently resuspend each red blood cell button. **
24. Read and record the results obtained.

** Suggested centrifugation time of 15 to 30 seconds at 900 to 1000 x g or a time and speed appropriate for the centrifuge used (that produces the strongest reaction of antibody with antigen positive red blood cells but yet allows easy resuspension of antigen negative red blood cells).

**Stability of Reaction:**
Following centrifugation, all tests should be read immediately and results should be interpreted without delay. Delays may result in dissociation of antigen-antibody complexes leading to falsely negative, or at most, weakly positive reactions.

Automation reads and interprets the results immediately.

## Interpretation of Results:

**Automated Method**
For the interpretation of results associated with automated instrumentation, refer to information provided in the instrument operator manual.

**Manual Method**
The expected results with corQC EXTEND reagents are listed in the table below. Results obtained in actual testing should be compared to this table. Each set of results should be compared to those obtained with the previous set of results. The strengths of the reactions on any run should be comparable to those indicated in this package insert and should be consistent in strength from run to run when the same lots of serum and red blood cell reagents are being tested. Test results that differ significantly from the expected, or results which vary greatly from run to run are an indication that the reagents or techniques being evaluated in quality control testing are not satisfactory. A significant and verified decrease in the strength of reactions with any reagent should be evaluated since it can be an indication of reagent deterioration or equipment malfunction.

| Tube | Reagent under Test | corQC EXTEND reagent | Average expected results | Test confirms |
|---|---|---|---|---|
| 1 | Anti-C | 1 | 2 – 4+ | Reactivity of Anti-C |
| 2 | Anti-c | | 2 – 4+ | Reactivity of Anti-c |
| 3 | Anti-E | 2 | 2 – 4+ | Reactivity of Anti-E |
| 4 | Anti-e | | 2 – 4+ | Reactivity of Anti-e |
| 5 | Anti-CDE | 1 | 2 – 4+ | Reactivity of the Anti-C component |
| 6 | Anti-CDE | 2 | 2 – 4+ | Reactivity of the Anti-E component |
| 7 | Anti-K | 3 | 2 – 4+ | Reactivity of Anti-K |
| 8 | Anti-C | 3 | Negative | Specificity of Anti-C |
| 9 | Anti-c | Standard | Negative | Specificity of Anti-c |
| 10 | Anti-E | 3 | Negative | Specificity of Anti-E |
| 11 | Anti-e | 4 | Negative | Specificity of Anti-e |
| 12 | Anti-CDE | 3 | Negative | Specificity of the Anti-C and Anti-E components |
| 13 | Anti-K | 1 | Negative | Specificity of Anti-K |
| 14 | Anti-D | Standard | 2 – 4+ | Reactivity of Anti-D |
| 15 | Anti-D | 3 | Negative | Specificity of Anti-D |
| 16 | Rh control material | 3 | Negative | Specificity of Rh control material |

## Limitations:

Quality control tests do not provide absolute assurance that false results will not occur in the actual use of blood bank reagents. Falsely negative or falsely positive test results can occur from bacterial or chemical contamination of test materials. In the manual method, falsely negative or falsely positive test results may be the result of inadequate incubation time or temperature, improper centrifugation, improper storage of materials or omission of test reagents.

corQC EXTEND reagents are intended for use in tests to determine the reactivity of routinely used blood bank reagents. The reagents are not designed for use with in vitro diagnostic tests (with patient or donor samples), unless incorporated as a run control for automated assays.

In manual testing, reactions obtained in quality control testing that are weaker than the average expected reactions described in this package insert are unacceptable. Factors contributing to unacceptable results include deterioration of the routine reagent under evaluation, suboptimal performance of test equipment such as washing devices and centrifuges, or poor testing technique of the operator. Less frequently, unacceptable results are an indicator of failure of the quality control reagents themselves. When the results of any quality control test fails to meet expectations, the test should be repeated. Repeated failures necessitate a thorough investigation to identify the cause and to eliminate it.

The reactivity of corQC EXTEND reagents may tend to diminish over the dating period.

## Specific Performance Characteristics:

Prior to release, each lot of corQC EXTEND Reagent Red Blood Cells are tested with licensed FDA reagents from two or more sources to insure that the product produces acceptable results. Each red blood cell sample is shown to have a negative direct antiglobulin test. When properly stored and used according to standard procedures, these reagents will demonstrate the appropriate antigens specified in the reagent description. The performance of this product is dependent upon adhering to the insert's recommended methodology. For additional information or for technical support, contact Immucor at 855-IMMUCOR (466-8267).

## Bibliography:


1. Brecher ME, ed. Technical manual. 15th ed. Bethesda MD: AABB, 2005.
2. Taswell HF. Error production and its control, In: A seminar on performance evaluation. Washington DC: American Association of Blood Banks, 1976: 115-120.
3. CLIA Reagent Quality requirements clarified. Newsbriefs, Bethesda, MD: American Association of Blood Banks, 1993;14 (3): 1.


## Symbols Glossary:

The Symbols Glossary (ID No. 400) is provided electronically at http://adextranet.immucor.com/EN/Pages/PackageInserts.aspx

Key:
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