User’s Guide

Web Based Application

Pediatric Urea Hydrolysis Rate Calculation (pUHR-CA) Version 2.0

A Companion Tool for the BreathTek® UBT for H. pylori Test in Pediatric Patients

For IVD use only
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I. INTRODUCTION

A. Intended Use

The Pediatric Urea Hydrolysis Rate Calculation Application is intended for use in the calculation of the Urea Hydrolysis Rate (UHR) as an aid for the initial diagnosis and post-treatment monitoring of *Helicobacter pylori* (*H. pylori*) infection in pediatric patients ages 3 to 17 years of age.

The application utilizes the results obtained from the BreathTek® UBT for *H. pylori* kit analyzed on the UBIt®-IR300 or POCon® Infrared Spectrophotometer, and the age, gender, height and weight of the pediatric patient. The application is accessed via the internet through a secure web browser in order to calculate the UHR.

B. Urea Hydrolysis Rate

For the BreathTek® UBT for *H. pylori* (BreathTek UBT), the cutoff point used to distinguish *H. pylori* positive from *H. pylori* negative results in adult patients has historically been expressed in terms of Delta Over Baseline (DOB). This parameter measures difference between the ratios of $^{13}\text{CO}_2$/$^{12}\text{CO}_2$ before and after administration of $^{13}$C-labeled urea. However, it has been shown that the measured DOB is a function of anthropometric variables, which, in turn, determine the rate of CO$_2$ production. While the effect of the CO$_2$ production rate on DOB is small in adults, it can be significant in children whose height and weight vary greatly from infancy to 18 years of age.

Consequently, the preferred metric for use in the diagnosis of *H. pylori* infection with BreathTek UBT in children is the UHR, which takes anthropometric variables into account. A cutoff value of 10 µg/min for the UHR has been established for the BreathTek UBT test for *H. pylori*. A UHR of $\geq$ 10 µg/min is considered positive for *H. pylori* infection. A UHR of < 10 µg/min is considered negative for *H. pylori* infection.

Since the calculation of UHR is complex, OAPI provides a web-based UHR calculation program described in this User’s Guide to facilitate the calculation of the UHR by healthcare professionals.
C. System Validation

The system has been validated for performance with Chrome, Firefox, and Internet Explorer Browsers.

D. Patient Privacy

The HIPAA Privacy Rule (Privacy Rule) establishes national standards to protect individuals' medical records and other personal health information and applies to health plans, healthcare clearinghouses, and those healthcare providers that conduct certain healthcare transactions electronically. The Privacy Rule requires appropriate safeguards to protect the privacy of personal health information, and sets limits and conditions on the uses and disclosures that may be made of such information without patient authorization.

Due to the Privacy Rule, the patient records are not saved on the Otsuka America Pharmaceutical, Inc. (OAPI) server. OAPI cannot retrieve any patient information for you.

E. Technical Support

OAPI-Medical Device Division - Technical Support Services

Toll-free Help Line: 1-888-637-3835
II. How to use the pUHR-CA
   A. Using the Application for the First Time

   Start your Internet Browser. Go to: http://www.breathekkids.com

   Figure 1 (Login Screen)

   ![Login Screen](image)

   Click on the “Register” button link and the following Registration screen Access screen (Figure 2) will appear:
Figure 2 (Registration Screen)

Enter the following information:
1) Account Name (i.e., your institution Account Name)
2) Account Number (i.e., your institution Account Number)
3) Requestor's Name (i.e., your first and last name)
4) Specialty (i.e. Pediatrics, Internal Medicine, Gastroenterology, Clinical Laboratory Technician, Other)
5) City (i.e., Account City)
6) State (i.e., Account State)
7) Phone
8) Business e-mail (your business e-mail address is preferred)

Click the Request Access button to submit your request.

After your credentials have been verified by the OAPI Medical Device Division, your User ID (i.e., your business e-mail address) and temporary password will be sent to you via the e-mail address you provided. This may take up to 48 hours. If you have not received the link with 48 hours, please contact Technical Support, 1-888-637-3835

After navigating to the puUHR-CA application link, the following screen (Figure 3) will appear and you will be prompted to enter a new password.
After you setting up your password, the application will take you back to the Log-in screen (Figure 1). After entering valid credentials, the application will take you to following Disclaimer window (Figure 4).
Read the Disclaimer and click on the “I Agree” button to proceed. You must accept the Disclaimer to gain access to the application.

Click on the “I Disagree” button if you don’t want to continue to the puHHR-CA.

After you have accepted the Disclaimer, the following UHR Calculator screen (Figure 5) will appear:

**Figure 5 (UHR Calculator Screen)**
B. Calculating the Urea Hydrolysis Rate

Confirm that you are on the UHR Calculation screen and the UHR Calculator tab has been selected. Otherwise, log into the pUHR-CA website by going to: [http://www.breathtekkids.com](http://www.breathtekkids.com) and complete the Log-in steps.

Enter the required information in the Input Data text boxes (all highlighted information is required, see Table 1 for entry format). Enter the information indicated in each of the boxes and select the appropriate ‘units’ options for age, height, and weight. Obtain the DOB result from the analysis of the samples on the UBiT-IR300 or PO Cone Infrared Spectrophotometer.

Information entered is subject to the following criteria:

**Entry Format for Input Data (Table 1)**

<table>
<thead>
<tr>
<th>Input Box</th>
<th>Acceptability Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barcode</td>
<td>Up to 15 digits</td>
</tr>
<tr>
<td>Collection Date</td>
<td>Select from pop up calendar</td>
</tr>
<tr>
<td>Analysis Date</td>
<td>Select from pop up calendar</td>
</tr>
<tr>
<td>Patient ID</td>
<td>2 to 15 Alpha and/or Numeric Characters</td>
</tr>
<tr>
<td>Delta Over Baseline</td>
<td>-2.0 to 250</td>
</tr>
<tr>
<td>Gender</td>
<td>Choose Male or Female</td>
</tr>
<tr>
<td>Age</td>
<td>3 to 17 years (36 to 215 months)</td>
</tr>
<tr>
<td>Height</td>
<td>11.8 inches to 8.2 feet (30 to 250 centimeters)</td>
</tr>
<tr>
<td>Weight</td>
<td>2 pounds to 507 pounds (0.9 to 230 kilograms)</td>
</tr>
</tbody>
</table>

Click the ‘Calculate UHR’ button to display the results as shown in the UHR Calculation Result screen (Figure 6) as shown below.

You can click the “Clear Form/New Calculation” button to clear all the data entry fields in order to do a calculation.
C. Saving Patient Data

You can save the UHR Calculation result temporarily in your login session by clicking the “Save Data Temporarily” button on the Result screen. After saving the result, the following message will appear:

Record saved temporarily. You will have the option to save changes permanently to your local computer prior to logging out.

Important! Due to the Privacy Rule (refer to section I – D of this User’s Guide), the system will not be able to store patient records on the Otsuka America Pharmaceutical, Inc. (OAPI) network/server. Also, the system will not allow OAPI to retrieve any patient related information.
Warning! If you do not save the data generated to your local computer before closing the session, the temporary data will be lost permanently.

D. To Permanently Save Your Data

Click on the “Save to Computer” button and follow the steps to store the results to the data file on your local computer permanently.

1. Click “Save” on the File Download window.
2. Navigate to the folder where you want to save the data file.
3. Click “Save” again and the UHR data will be saved to local folder selected for storage.

The patient result can now be retrieved at a later time.

E. Printing a Report from the Result Screen

1. Click the “Print” button on the Result Calculation Screen
2. The report displays in a new window (See Figure 7)
3. Click on the “Print” button to print the report (See Figure 7)
4. You will have the option to print the report, export/save the report to a disk as mentioned below:
   - Save as PDF file
   - Save as JPEG file
Figure 7 (Patient Report Displayed in a New Window)
F. Going back to UHR Calculator screen

You can navigate back to UHR Calculator screen by clicking either “Back to UHR Calculator” or “X” button in the upper right hand corner of the window (See Figure 6).

**Warning!** If you save data temporarily from the session, the UHR calculator screen will be cleared and ready for subsequent calculations. Otherwise, the input data will be retained and you must clear the data to perform a new calculation.

G. Pull Past Data

You have the option to upload a data file from your computer to append existing calculated records, any time during your session. To append, follow the steps below:

**Step 1:** Navigate to “Pull Past Data” tab.
**Step 2:** Click the “Browse” button to locate data file from your computer (See Figure 8)
**Step 3:** Click the “Pull Data” button to load/add all your existing calculated records in your login session (See Figure 8)

**Figure 8 (Pull Past Data)**

**Warning!** You can upload a data file one-time only to your current login session. If you wish to change a data file, logout then log back in.
H. Retrieving Patient Data

Click on the “Records” tab and the Records screen will appear (See Figure 9).

Figure 9 (Search Existing Records Screen)

- In default, all records will be displayed sequentially by calculation date and time.
- Patient data records that have been uploaded or saved in current session can be retrieved by searching with a full or partial **Barcode number**, **Patient ID**, or **User Name**.
- To search for a record(s) by **Barcode number**, enter the Barcode number in the Search field then click on the button to the right of this field. If you enter part of the number, all records that contain the matching sequence of numbers will be displayed.
To search for a record(s) by **Patient ID**, enter the Patient ID in the Search field then click on the button to the right of this field. The first record with the desired patient ID will be displayed. If you enter part of the ID, all records that contain the matching sequence of letters or numbers will be displayed.

To search for a record(s) by **User name**, enter the User name in the Search field then click on the button to the right of this field. The first record with the User name will be displayed. If you enter part of the User name, all records that contain the matching sequence of letters or numbers will be displayed.

Choose the record(s) you wish to print by selecting the checkbox(s) to the left of each record and then click on “Print Selected” button on the upper right hand corner of the window. All selected records will be printed.

You can also print a single report by clicking the icon to the right of the Calculation Date of that record. **Please refer to step D of this section for additional print instructions.**

In default, first 10 data records will be displayed sequentially by calculation date and time per page. You can navigate to subsequent set of records by clicking the respective paging buttons (First Previous < 1 2 3 4 > Next Last) on the lower left hand corner of the window.

Click on the “Save All to Computer” button to store all the records to a file on your local computer. (**Note: Irrespective of checkbox(s) selection, all records will be saved**) 

**1. Logging Out of the System**

Having completed all the tasks, click on “Logout” button in the upper right hand corner of the window.

**Note:** If the current session data not saved early, you will be prompted to save to your computer and the following message will appear:

Please save your data to computer before you logout, otherwise the data from the current session will be lost.
### III. Troubleshooting

<table>
<thead>
<tr>
<th>Issue</th>
<th>Resolution</th>
</tr>
</thead>
<tbody>
<tr>
<td>System does not accept my User ID or Password</td>
<td>Select “Reset Password” for your user ID and a new password. Remember your user ID is your e-mail address.</td>
</tr>
<tr>
<td>UHR Log-in screen does not appear</td>
<td>Confirm that you are connected to your browser.</td>
</tr>
<tr>
<td>I do not have access to the calculation</td>
<td>Select the “Request Access” button, enter all requested details and click Request Access button. You will receive the email to gain access to the system upon approval.</td>
</tr>
<tr>
<td>I cannot find my data file</td>
<td>Confirm the file name with the extension ‘uhr’.</td>
</tr>
<tr>
<td>I cannot locate the patient record</td>
<td>Confirm that you have saved the patient record to data file.</td>
</tr>
<tr>
<td>System does not accept the Barcode number</td>
<td>Confirm that the bar code number is not associated with another patient record. Note: You may enter up to 15 digits.</td>
</tr>
<tr>
<td>System will not accept analysis date</td>
<td>Confirm that the date entered is within 7 days of the sample collection date.</td>
</tr>
<tr>
<td>The DOB is less than -2.0 % and the system will not accept the DOB result</td>
<td>Call Technical Support 1-888-637-3835.</td>
</tr>
<tr>
<td>All the information entered appears to meet the acceptability criteria, but the following message appears: please provide valid data for all required fields</td>
<td>Confirm that you have selected Male or Female under the DOB field and verify that all fields have been entered.</td>
</tr>
<tr>
<td>The UHR calculation result is not what I expected</td>
<td>Confirm that all data was entered correctly. If all data was entered correctly, consult with the patient’s physician.</td>
</tr>
</tbody>
</table>

- You may also click on the User’s Guide link located in the upper right hand corner of the screen to access the User’s Guide of the application.

- You may also view the disclaimer content anytime during your login, by clicking Disclaimer link provided in the upper right hand corner of the screen.
You can reach out to technical support anytime during your login, by clicking either Click here or Technical Support of the link ("Click here to contact Technical Support with questions or problem") provided in the bottom right corner of the screen.

J. References


Trademarks

BreathTek® is registered trademark of Otsuka America Pharmaceutical, Inc.

UBiT®-IR300 and PO Cone® are registered trademarks of Otsuka Pharmaceutical Co., Ltd.

Name and Place of Business

The $p$UHR-CA is manufactured by:
Otsuka America Pharmaceutical, Inc. (OAPI)
2440 Research Blvd
Rockville, Maryland 20850

Labeling Revision Information

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