

RaPET-Lab/AR

AR-2000 Radiochromatography Workflow Management Software

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Reliable and easy-to-use software for GMP compliant AR-2000 radiochromatography



Introduction

The AR-2000 radio-TLC imaging scanner is considered an industry standard for TLC radiochromatography. This scanner can be used with any radionuclide emitting ionizing radiation (alpha, beta, positron, gamma). We offer two software solutions with this scanner; Win-Scan and RaPET-Lab/AR. Win-Scan, the venerable software for the AR-2000, is predominantly used by labs that do not require GMP compliance. RaPET-Lab/AR solves the compliance issue and provides a modern software platform for AR-2000 users. RaPET-Lab/AR or RPLAR software, is a workflow management tool for automated execution of full processes of measurement, evaluation and quality checks using the AR-2000. Tasks for desired processes can be integrated and executed in a predetermined order. All steps of the workflow are evaluated in an automatically generated unchangeable report. Most importantly the software is 21CFR part 11 compliant.

Functionality

The user can create workflows consisting of several tasks with the ability to edit, run and review them. The software can be used in two different modes: Edit and Run.

The Edit mode requires special user permission and makes available the creation and insertion of workflows, the change of settings and deletion of tasks as well as the changing of report settings and templates. Entire workflows can be saved with source control. In Run mode prepared workflows can be set, paused, canceled and reviewed. Reports can be viewed, exported or printed. Aside from workflow usage single tasks can be opened and run. Measurement Tasks are opened to perform an acquisition of an AR-2000 radiochromatogram. Evaluation Tasks are opened to evaluate a previously collected radiochromatogram. Standard automated peak searches are performed with the Evaluation Task as well as manual selection of peaks.

A typical workflow for a radiopharmaceutical will consist of the following:

Job Task: Identify the batch using automatic or user-specified batch numbers. The user can also add a preparation checklist to make sure all pre-acquisition steps are followed.

Measurement Task: AR-2000 measurement. The user will specify all acquisition parameters normally found in Win-Scan and more; including number of lanes, acquisition time, type of head movement, number of channels, electronic resolution settings, etc.

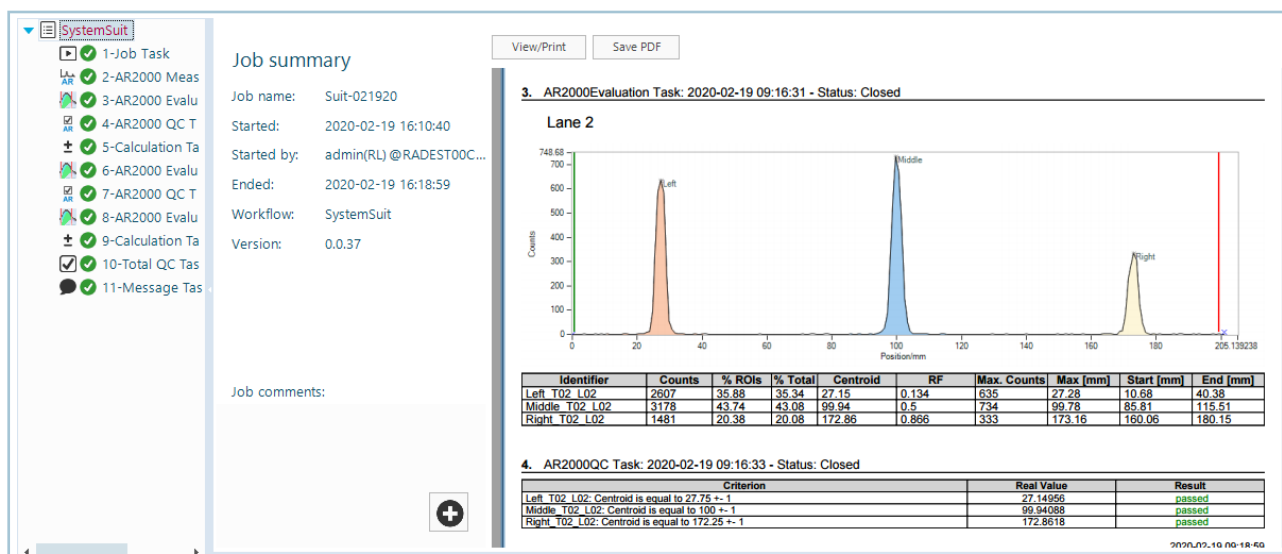
Evaluation Task: The radiochromatogram from the measurement task is passed to the Evaluation Task for processing. Peaks are identified automatically with search criteria, manually or a combination of both. Background subtraction, smoothing and normalization are added, if selected. Peak identification is obtained so that product and impurities can be identified.

QC Task: The results of the Evaluation Task are put through a QC filter to determine if the results meet user-specified acceptance criteria. Pre-defined operations such as percentage activity in a region, location of a peak, retention factor (rf), etc. are QC parameters available to the user.

Calculation Task (optional): In most instances the standard QC Task is sufficient to obtain pass/fail data. However, sometimes users will require additional parameters and need to make calculations for special acceptance criteria. The Calculation Task can help accomplish this.

Total QC Task (optional): The Total QC Task consolidates the results of the QC Task(s) and Calculation Task(s) if necessary to create a Total QC result that includes all QC and calculations.

DISCLAIMER: This is original material from Eckert & Ziegler and has not been altered in any way by Bayer.



Screenshot of RaPET-Lab/AR Software

Reporting

A user-customizable workflow report is obtained which shows the results of each task and QC results. The report may include signature fields and be branded with resident facility logos and other images for an easily recognizable visible reference.

System Suitability

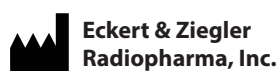
RaPET-Lab/AR also includes a standard workflow that can be used as a system suitability test for your AR-2000. It utilizes the normalization, linearity and resolution lanes of the AR-2000 calibration plate and compares the results to specifications from the AR-Calib software and normal AR QC parameters. Each test is checked and a Total QC Task result is generated in a report, making the system suitability automated and easy.

GMP Compliance

RaPET-Lab/AR software is compliant with the highest standards of GMP, cGMP, GAMP 5 and 21 CFR part 11 regulations. The software contains built-in user management for login and restricted access to certain functions of the software. Permissions are assigned to groups. All actions are tracked in an audit trail and all projects, reports and methods are source controlled with a version number (automatically or manually incremented). Deletion or change of data within the database is impossible due to access protection.

Computer Specifications

Processor	I5 Processor, 2.66 GHz or faster 32-bit (x86) or 64-bit (x64) dual core processor
RAM	4 GB or more
Hard Drive	250 GB, HDD or SSD
Display	15" Full HD (1920 x 1080), non-touch
Operating System	Windows 10 Professional (64-bit recommended)
USB	3 USB Ports (mouse, usb-rs232 adapter, usb dongle)
Connection	LAN or WiFi connection to internet for remote diagnostic support
Optional	Direct RS-232 port



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