



RN SI 287 Zenit Pro SW Ver. 1.5.45

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|---------------|----------------------|--------------|-----------------------------------|
| Codice/Code | Revisione / Revision | Stato/Status | Approvato in data / Approval date |
| QUE-000074078 | 1.0, CURRENT | Approved | 7-Jul-2021 |

| | | | |
|-----------|---------------------------------|---------------------|---------------------------|
| PRODUCT | Zenit Pro | DATE | 07/07/2021 |
| AUTHOR | A. Salamone | SOURCE | Visia Lab srl |
| MANDATORY | Yes | TO BE CARRIED OUT | First Service Call |
| SERIAL N° | All | STANDARD TASK HOURS | 1 |
| SUBJECT | Zenit Pro SW Ver. 1.5.45 | | |

Note :

New SW Ver. 1.5.45 for Zenit Pro instrument has been released and it is now available in www.servicemd.eu

For downloading it, enter in the dedicated area:
Autoimmunity > Technical Service - Analysers - Zenit Pro > Doiwnload
File to download: **update-zenitpro-1.5.45.zip**

This document contains as attachment all the sw release notes from ver. 1.5.41 to the actual ver. 1.5.45.
To update the sw, just follow the instructions shown in the operator manual, chapter 13.30 (which is also attached to this document).

Be aware: for instrument with SN up and included 0037, if at its first installation at customer site please, refer to the instructions of RN SI 261.

Note:

On Field Service Management System as been implemented a dedicated problem code:
RN SI 287 Zenit Pro SW Ver. 1.5.45

| | |
|------------|---|
| ATTACHMENT | Zenit PRO-ReleaseNotes-up to 1.5.45.pdf Zenit PRO install updates instructions.pdf |
|------------|---|



Electronic Signatures

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| Document Number | Version | Status | Approved Date* |
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| QUE-000074078 | 1.0, CURRENT | Approved | 7-Jul-2021 |
| LegacyNumber | | AuthorName | |
| | | Salamone Alfonso Alessandro | |

*based on server time zone

| User | Date | Justification |
|------------------|----------------------------------|------------------|
| Vaccaro Girolamo | 07-Jul-2021 13:37:15 (GMT) | Manager Approval |

| | | | |
|--------------------|-----------------|---|------------------|
| PROJECT ID | PR_M_20140318_1 | PRODUCT | Zenit PRO |
| REVISION N. | 1 | DATE | 10/03/2021 |
| SW version | 1.5.41 | Note | |
| | NAME | ROLE | SIGNATURE |
| PREPARED BY | M. MEONI | R&D Manager and Project Leading | |
| VERIFIED BY | G. DONATI | Technical Office, Design & Engineering Manager | |
| APPROVED BY | S. FANTECHI | Operation & QA/RA Manager | |

REVISION HISTORY

| Revision Number | Revision Date | Revision Note |
|-----------------|---------------|----------------|
| 1 | 10/03/2021 | First emission |

Zenit PRO – Software version 1.5.41

1. Minor defects corrected and minor features introduced in software version 1.5.41 (since last official release 1.5.40)

| Defect/Feature | Description |
|----------------|--|
| GP-2359 | Processing position added to HL7 Lis communication protocol for Scan Only sessions |

2. Known unresolved anomalies in software version 1.5.41

| Defect | Description | Workaround / Preventative Measure |
|---------------|---|---|
| GP-1579 | Multi-touch gestures (e.g. the pinch to zoom) are not "fluid" | NA |
| GP-1705 | Camera firmware is not upgradable with the system upgrader | Upgrade it manually |
| GP-2016 | Ability to insert manually the barcode of the slides in the processing wizard | NA |
| GP-2008 | Well history: add user information for retry/ignore commands | NA |
| GP-2053 | Inserting racks very fast could cause UI wrong update during the "Auto assign" function | The software works properly, just UI error. Close the Load Rack interface, and reload again to view the correct interface |

| | | | |
|--------------------|-----------------|---|------------------|
| PROJECT ID | PR_M_20140318_1 | PRODUCT | Zenit PRO |
| REVISION N. | 1 | DATE | 22/03/2021 |
| SW version | 1.5.42 | Note | |
| | NAME | ROLE | SIGNATURE |
| PREPARED BY | M. MEONI | R&D Manager and Project Leading | |
| VERIFIED BY | G. DONATI | Technical Office, Design & Engineering Manager | |
| APPROVED BY | S. FANTECHI | Operation & QA/RA Manager | |

REVISION HISTORY

| Revision Number | Revision Date | Revision Note |
|-----------------|---------------|----------------|
| 1 | 22/03/2021 | First emission |

Zenit PRO – Software version 1.5.42

1. Minor defects corrected and minor features introduced in software version 1.5.42 (since last official release 1.5.41)

| Defect/Feature | Description |
|----------------|--|
| GP-2362 | Template image changed for Anca 6 wells slides |
| GP-2362 | Ability to set multiple images paths for external viewer |

2. Known unresolved anomalies in software version 1.5.42

| Defect | Description | Workaround / Preventative Measure |
|---------------|---|---|
| GP-1579 | Multi-touch gestures (e.g. the pinch to zoom) are not "fluid" | NA |
| GP-1705 | Camera firmware is not upgradable with the system upgrader | Upgrade it manually |
| GP-2016 | Ability to insert manually the barcode of the slides in the processing wizard | NA |
| GP-2008 | Well history: add user information for retry/ignore commands | NA |
| GP-2053 | Inserting racks very fast could cause UI wrong update during the "Auto assign" function | The software works properly, just UI error. Close the Load Rack interface, and reload again to view the correct interface |

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|--------------------|-----------------|---|------------------|
| PROJECT ID | PR_M_20140318_1 | PRODUCT | Zenit PRO |
| REVISION N. | 1 | DATE | 26/05/2021 |
| SW version | 1.5.44 | Note | |
| | NAME | ROLE | SIGNATURE |
| PREPARED BY | M. MEONI | R&D Manager and Project Leading | |
| VERIFIED BY | G. DONATI | Technical Office, Design & Engineering Manager | |
| APPROVED BY | S. FANTECHI | Operation & QA/RA Manager | |

REVISION HISTORY

| Revision Number | Revision Date | Revision Note |
|-----------------|---------------|----------------|
| 1 | 26/05/2021 | First emission |

Zenit PRO – Software version 1.5.44

1. Minor defects corrected and minor features introduced in software version 1.5.44 (since last official release 1.5.43)

| Defect/Feature | Description |
|----------------|--|
| GP-2372 | Bug fixed on lis scanning session with multiple slides and empty wells |
| GP-2373 | Duplicated sample info added on Full Run Wizard |

2. Known unresolved anomalies in software version 1.5.44

| Defect | Description | Workaround / Preventative Measure |
|---------|---|---|
| GP-1579 | Multi-touch gestures (e.g. the pinch to zoom) are not "fluid" | NA |
| GP-1705 | Camera firmware is not upgradable with the system upgrader | Upgrade it manually |
| GP-2016 | Ability to insert manually the barcode of the slides in the processing wizard | NA |
| GP-2008 | Well history: add user information for retry/ignore commands | NA |
| GP-2053 | Inserting racks very fast could cause UI wrong update during the "Auto assign" function | The software works properly, just UI error. Close the Load Rack interface, and reload again to view the correct interface |

| | | | |
|--------------------|-----------------|---|------------------|
| PROJECT ID | PR_M_20140318_1 | PRODUCT | Zenit PRO |
| REVISION N. | 1 | DATE | 01/06/2021 |
| SW version | 1.5.45 | Note | |
| | NAME | ROLE | SIGNATURE |
| PREPARED BY | M. MEONI | R&D Manager and Project Leading | |
| VERIFIED BY | G. DONATI | Technical Office, Design & Engineering Manager | |
| APPROVED BY | S. FANTECHI | Operation & QA/RA Manager | |

REVISION HISTORY

| Revision Number | Revision Date | Revision Note |
|-----------------|---------------|----------------|
| 1 | 01/06/2021 | First emission |

Zenit PRO – Software version 1.5.45

1. Minor defects corrected and minor features introduced in software version 1.5.45 (since last official release 1.5.44)

| Defect/Feature | Description |
|----------------|--|
| GP-2377 | Bug fixed on lis scanning session with multiple slides and empty wells |

2. Known unresolved anomalies in software version 1.5.45

| Defect | Description | Workaround / Preventative Measure |
|---------------|---|---|
| GP-1579 | Multi-touch gestures (e.g. the pinch to zoom) are not "fluid" | NA |
| GP-1705 | Camera firmware is not upgradable with the system upgrader | Upgrade it manually |
| GP-2016 | Ability to insert manually the barcode of the slides in the processing wizard | NA |
| GP-2008 | Well history: add user information for retry/ignore commands | NA |
| GP-2053 | Inserting racks very fast could cause UI wrong update during the "Auto assign" function | The software works properly, just UI error. Close the Load Rack interface, and reload again to view the correct interface |



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Electronic Signatures

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| QUE-000074085 | | | |
| LegacyNumber | | AuthorName | |
| | | Salamone Alfonso Alessandro | |

*based on server time zone

| User | Date | Justification |
|------------------|----------------------------------|------------------|
| Vaccaro Girolamo | 07-Jul-2021 13:37:27 (GMT) | Manager Approval |

13.30 Install Updates

Install the updates from a USB.

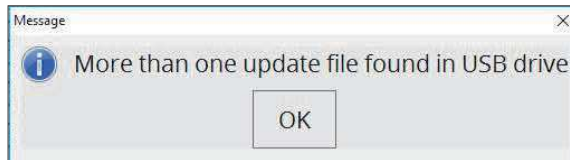
The user must insert an USB containing the Update file zip and select the “Install Updates” option

 from the Configuration Module. A pop up window will appear asking if you want to proceed with the upgrade process.

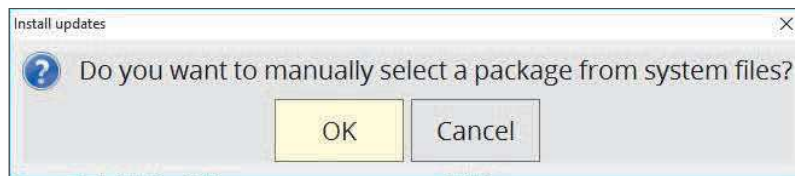


Tap ok to apply the update.

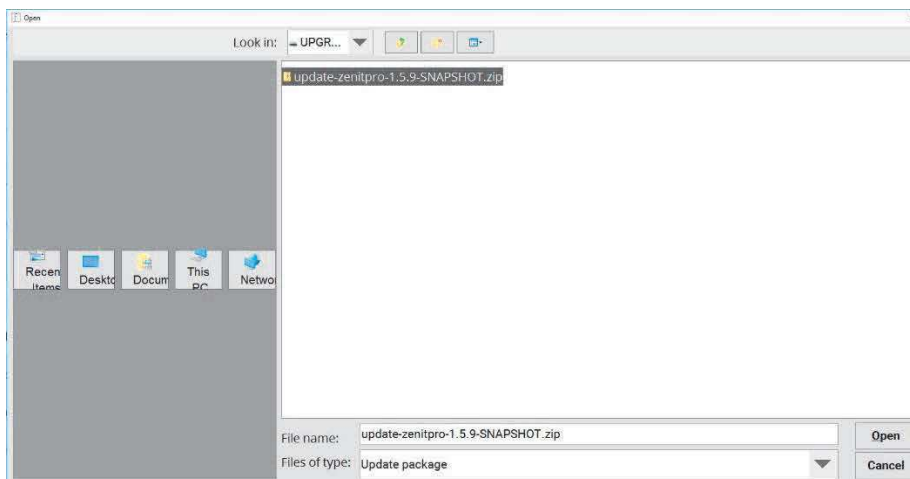
If no update zip file is found, or more than one are found in the USB, a message will warn the User.



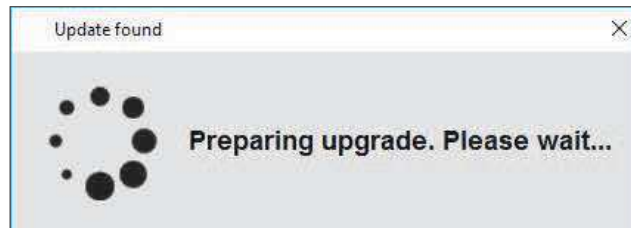
Tapping ok a new pop up appears asking if you want to select manually the required update file.



Tapping ok a window will appear allowing the User to manually select the specific update zip file he wants to apply.



Once the update is selected manually by the user or automatically by the system (if only one update zip file was found) the system will prepare for the upgrade and the following message will appear.



At the end of the loading process another pop up will appear asking the User to restart the system to apply the update.



Tap ok to proceed. The system will restart and launch the upgrade. At the end of the upgrade process the system will start normally and show the log in interface.

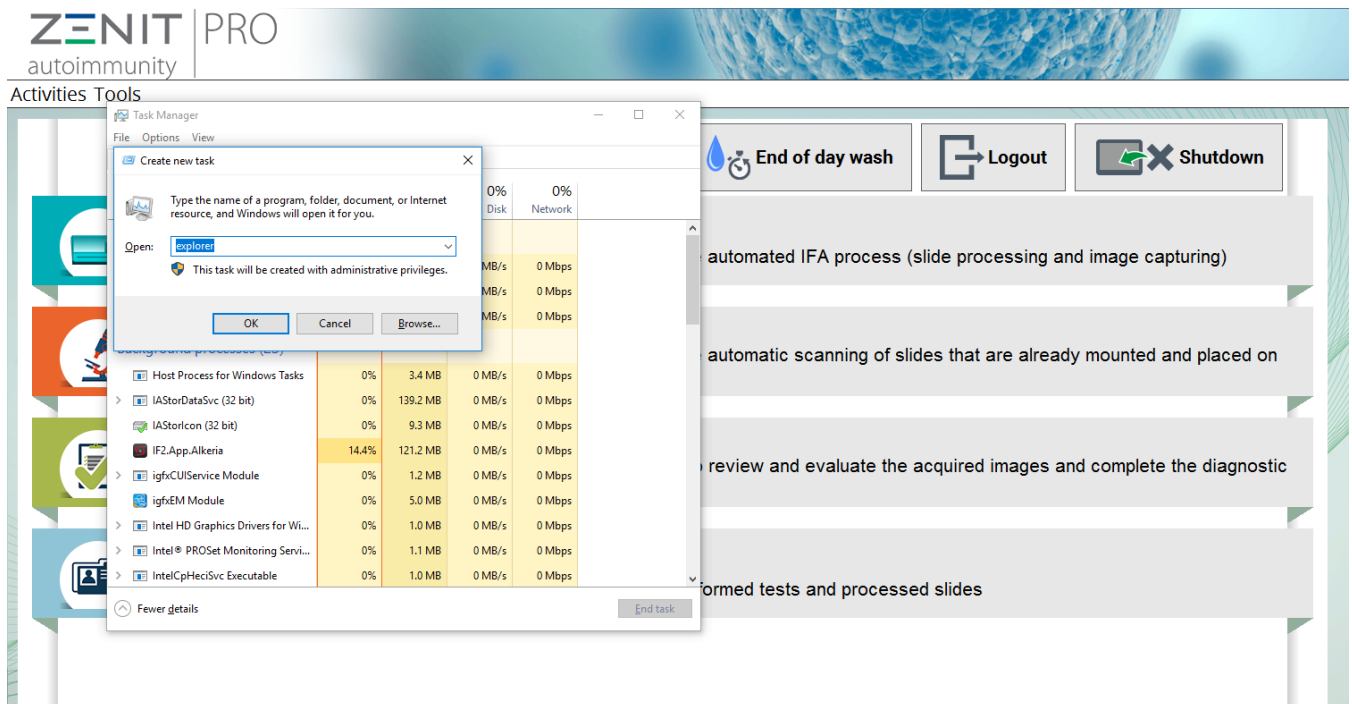
Tool update atlas and pattern

The devices involved have a serial number lower 116200038.



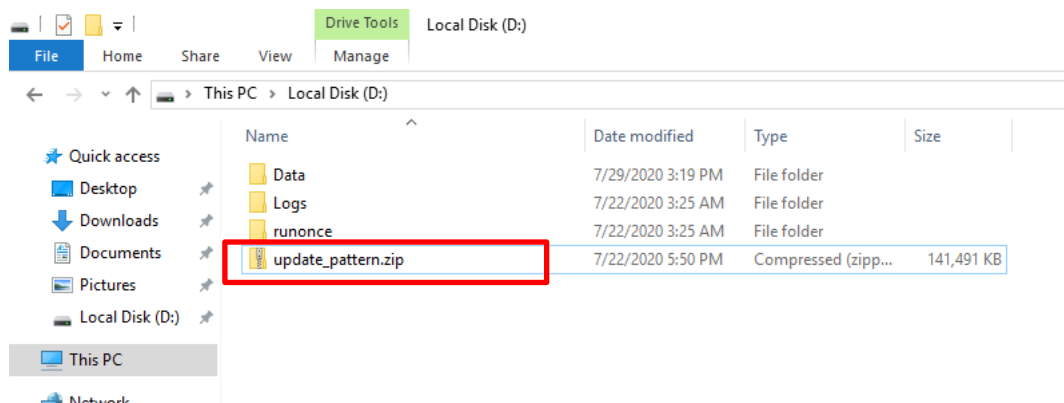
The tool is intended to be used only during the first instrument installation in the customer site and just after the update of the SW to the latest version available.
If the update is run on system where there are sessions with pattern assigned the association will be lost

- In the main menu, open the “task manager” pressing Ctrl+shift+esc on the keyboard
- Press file and types explorer in order to open Windows explorer

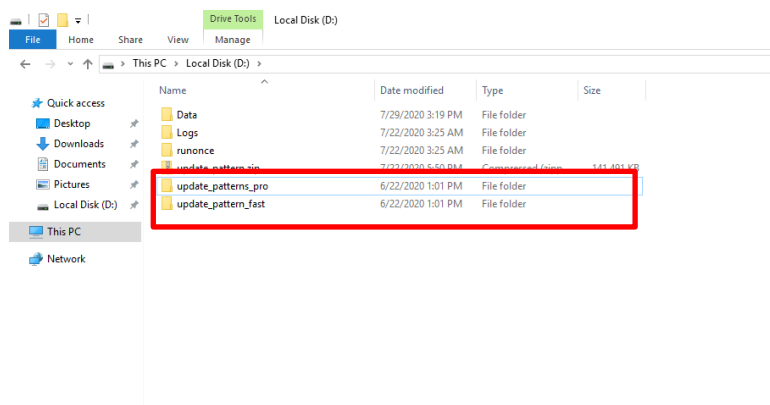


The screenshot shows the ZENIT PRO software interface with the Windows Task Manager and a file explorer window open. The Task Manager window displays a list of running processes, including Host Process for Windows Tasks, IAStorDataSvc (32 bit), IAStorIcon (32 bit), IF2.App.Alkeria (14.4%), igfxCUIService Module, igfxEM Module, Intel HD Graphics Drivers for Wi..., Intel® PROSet Monitoring Servi..., and IntelCpHeciSvc Executable. The file explorer window shows the 'Open:' field with 'explorer' entered. The software interface also features buttons for 'End of day wash', 'Logout', and 'Shutdown', and a list of automated processes such as 'automated IFA process (slide processing and image capturing)', 'automatic scanning of slides that are already mounted and placed on', 'review and evaluate the acquired images and complete the diagnostic', and 'ormed tests and processed slides'.

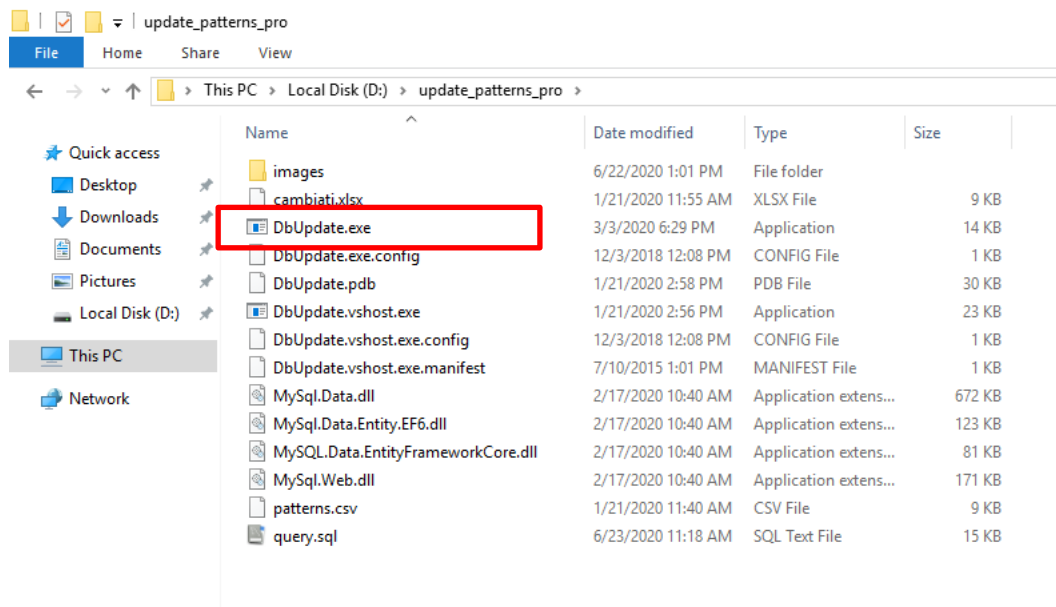
- Copy the folder update_pattern.zip on D: disk



- Extract the Zip file
- Open the update_pattern_pro folder if the device is a ZENIT PRO or update_pattern_fast if the device is a ZENIT fast



- Execute DbUpdate.exe, located inside update_pattern.zip



Add image in atlas for a pattern

In this section, all the currently registered patterns are displayed.

| Name | Alias | Description | Test group |
|-------|------------------|------------------------------------|------------|
| AC-1 | Homogeneous | Homogeneous and regular ... | ANA |
| AC-10 | Nucleolar speck. | Densely distributed but dis... | ANA |
| AC-10 | NOR90 | Densely distributed but dis... | ANA |
| AC-11 | Lamin | Homogeneous staining of t... | ANA |
| AC-12 | Pore complex | Nuclear envelope reveals a ... | ANA |
| AC-13 | PCNA | Pleomorphic speckled nucl... | ANA |
| AC-15 | Actin | This pattern is characteriz... | ANA |
| AC-16 | Vimentin | Staining of microtubules an... | ANA |
| AC-16 | Keratin | Staining of microtubules an... | ANA |
| AC-18 | Lisosomial | Staining of GW bodies in th... | ANA |
| AC-19 | Ribosomal | The pattern appears cloudy... | ANA ANA |
| AC-19 | Cyto Speckled | The pattern appears cloudy... | ANA |
| AC-20 | Cito Fine speck. | Scattered small speckles in ... | ANA |
| AC-21 | Mitochondrial | Coarse granular filamentou... | ANA |
| AC-22 | Golgi | Discontinuous speckled or ... | ANA |
| AC-24 | Centriole | Distinct centrioles (1-2/cell) ... | ANA |
| AC-25 | Mitotic spindle | The spindle fibers between ... | ANA |
| AC-26 | NuMA | Nuclear speckled staining ... | ANA |
| AC-27 | Midbody | Staining of the intercellular ... | ANA |
| AC-3 | Centromere | Discrete coarse speckles (4... | ANA |
| AC-4 | Nuc. Fine speck | Fine tiny speckles across all | ANA |

Fig. 0-1: Patterns

Name The pattern name.


Alias The alias associated to the selected pattern. If a pattern has an alias, it will be used to identify the pattern instead of the pattern name in the software environment.

Description A brief description for the selected pattern

Test group The test group the pattern belongs to.

Create a new pattern entry.
In addition to Name, Alias,
description and test group the
user can associate an image to
the new pattern by tapping on



the  button or delete
an existing one by tapping on



New Patterns
Patterns



✘ The value cannot be an empty string

Name

Alias

Description


Test group

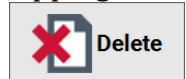
Images  

Image

Review and modify the
details for the selected
pattern.



By tapping on the  button the user can select a
new images to add in the atlas, open it and then press
“Save” or “Save and close”.
Selecting an already existing
image the user can delete it
tapping on the button





Modify Patterns
Patterns

Name AC-10

Alias Nucleolar speck.

Description **Densely distributed but distinct grains seen in the nucleoli of interphase cells.**
In metaphase cells, up to 5 bright spots of the nucleolar organizer regions



Test group ANA

Images  

Image



Permanently delete the selected pattern.

Tap on previous  or next  buttons to quickly move between the listed patterns.



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| QUE-000074088 | | | |
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| | Salamone Alfonso Alessandro | | |

*based on server time zone

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