

EUROPEAN PATENT OFFICE
U.S. PATENT AND TRADEMARK OFFICE

CPC NOTICE OF CHANGES 1118

DATE: AUGUST 1, 2021

PROJECT RP0422

The following classification changes will be effected by this Notice of Changes:

<u>Action</u>	<u>Subclass</u>	<u>Group(s)</u>
SCHEME:		
Symbols Deleted:	Y10S	435/96
Symbols New:	G01N	33/54387, 33/54388, 33/54389, 33/54391
	G01N	2470/00, 2470/04, 2470/06, 2470/10, 2470/12
	G01N	2474/00, 2474/10, 2474/20
Titles Changed:	G01N	33/558, 33/56988
	G01N	2800/52
Warnings New:	G01N	33/54386, 33/54387, 33/558
DEFINITIONS:		
Definitions New:	G01N	33/54387, 33/54388, 33/54391
Definitions Modified:	G01N	33/558

No other subclasses/groups are impacted by this Notice of Changes.

This Notice of Changes includes the following [Check the ones included]:

1. CLASSIFICATION SCHEME CHANGES

- A. New, Modified or Deleted Group(s)
- B. New, Modified or Deleted Warning(s)
- C. New, Modified or Deleted Note(s)
- D. New, Modified or Deleted Guidance Heading(s)

2. DEFINITIONS

- A. New or Modified Definitions (Full definition template)
- B. Modified or Deleted Definitions (Definitions Quick Fix)

3. REVISION CONCORDANCE LIST (RCL)

4. CHANGES TO THE CPC-TO-IPC CONCORDANCE LIST (CICL)

5. CHANGES TO THE CROSS-REFERENCE LIST (CRL)

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1. CLASSIFICATION SCHEME CHANGES

A. New, Modified or Deleted Group(s)

SUBCLASS G01N - INVESTIGATING OR ANALYSING MATERIALS BY DETERMINING THEIR CHEMICAL OR PHYSICAL PROPERTIES (measuring or testing processes other than immunoassay, involving enzymes or microorganisms C12M, C12Q)

<u>Type*</u>	<u>Symbol</u>	<u>Indent Level Number of dots (e.g. 0, 1, 2)</u>	<u>Title</u> <u>“CPC only” text should normally be enclosed in {curly brackets}**</u>	<u>Transferred to[#]</u>
C	G01N33/54386	6	{Analytical elements}	G01N33/54386, G01N33/54387, G01N33/54388, G01N33/54389, G01N33/54391
N	G01N33/54387	7	{Immunochemical test strips}	
N	G01N33/54388	8	{based on lateral flow}	
N	G01N33/54389	9	{with bidirectional or multidirectional lateral flow, e.g. wherein the sample flows from a single, common sample application point into multiple strips, lanes or zones}	
N	G01N33/54391	8	{based on vertical flow}	
C	G01N33/558	4	using diffusion or migration of antigen or antibody {(immunochemical test strips G01N 33/54387)}	G01N33/558, G01N33/54387, G01N33/54388, G01N33/54389, G01N33/54391
M	G01N33/56988	6	{HIV or HTLV}	
U	G01N 2469/20	1	Detection of antibodies in sample from host which are directed against antigens from microorganisms	
N	G01N 2470/00	0	Immunochemical assays or immunoassays characterised by the reaction format or reaction type	
N	G01N 2470/04	1	Sandwich assay format	
N	G01N 2470/06	2	Second binding partner specifically binding complex of analyte with first binding partner	
N	G01N 2470/10	1	Competitive assay format	
N	G01N 2470/12	2	Displacement or release-type competition	
N	G01N 2474/00	0	Immunochemical assays or immunoassays characterised by detection mode or means of detection	
N	G01N 2474/10	1	Immunoblots, e.g. Western blot or Dot blot	
N	G01N 2474/20	1	Immunohistochemistry assay	
U	G01N 2496/00	0	Reference solutions for assays of biological material	

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M	G01N 2800/52	1	Predicting or monitoring the response to treatment, e.g. for selection of therapy based on assay results in personalised medicine; Prognosis	
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*N = new entries where reclassification into entries is involved; C = entries with modified file scope where reclassification of documents from the entries is involved; Q = new entries which are firstly populated with documents via administrative transfers from deleted (D) entries. Afterwards, the transferred documents into the Q entry will either stay or be moved to more appropriate entries, as determined by intellectual reclassification; T= existing entries with enlarged file scope, which receive documents from C or D entries, e.g. when a limiting reference is removed from the entry title; M = entries with no change to the file scope (no reclassification); D = deleted entries; F = frozen entries will be deleted once reclassification of documents from the entries is completed; U = entries that are unchanged.

NOTES:

- **No {curly brackets} are used for titles in CPC only subclasses, e.g. C12Y, A23Y; 2000 series symbol titles of groups found at the end of schemes (orthogonal codes); or the Y section titles. The {curly brackets} are used for 2000 series symbol titles found interspersed throughout the main trunk schemes (breakdown codes).
- U groups: it is obligatory to display the required “anchor” symbol (U group), i.e. the entry immediately preceding a new group or an array of new groups to be created (in case new groups are not clearly subgroups of C-type groups). Always include the symbol, indent level and title of the U group in the table above.
- All entry types should be included in the scheme changes table above for better understanding of the overall scheme change picture. Symbol, indent level, and title are required for all types.
- “Transferred to” column must be completed for all C, D, F, and Q type entries. F groups will be deleted once reclassification is completed.
- When multiple symbols are included in the “Transferred to” column, avoid using ranges of symbols in order to be as precise as possible.
- For administrative transfer of documents, the following text should be used: “< administrative transfer to XX>”, “<administrative transfer to XX and YY simultaneously>”, or “<administrative transfer to XX, YY ...and ZZ simultaneously>” when administrative transfer of the same documents is to more than one place.
- Administrative transfer to main trunk groups is assumed to be the source allocation type, unless otherwise indicated.
- Administrative transfer to 2000/Y series groups is assumed to be “additional information”.
- If needed, instructions for allocation type should be indicated within the angle brackets using the abbreviations “ADD” or “INV”: <administrative transfer to XX ADD> , <administrative transfer to XX INV>, or < administrative transfer to XX ADD, YY INV, ... and ZZ ADD simultaneously>.
- In certain situations, the “D” entries of 2000-series or Y-series groups may not require a destination (“Transferred to”) symbol, however it is required to specify “<no transfer>” in the “Transferred to” column for such cases.
- For finalisation projects, the deleted “F” symbols should have <no transfer> in the “Transferred to” column.
- For more details about the types of scheme change, see CPC Guide.

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SUBCLASS Y10S - TECHNICAL SUBJECTS COVERED BY FORMER USPC CROSS-REFERENCE ART COLLECTIONS [XRACs] AND DIGESTS

<u>Type*</u>	<u>Symbol</u>	<u>Indent Level</u> <u>Number of dots</u> <u>(e.g. 0, 1, 2)</u>	<u>Title</u> <u>“CPC only” text should normally be</u> <u>enclosed in {curly brackets}**</u>	<u>Transferred to#</u>
D	Y10S 435/96	1	Immunohistochemical assay	<administrative transfer to G01N 2474/20>

*N = new entries where reclassification into entries is involved; C = entries with modified file scope where reclassification of documents from the entries is involved; Q = new entries which are firstly populated with documents via administrative transfers from deleted (D) entries. Afterwards, the transferred documents into the Q entry will either stay or be moved to more appropriate entries, as determined by intellectual reclassification; T= existing entries with enlarged file scope, which receive documents from C or D entries, e.g. when a limiting reference is removed from the entry title; M = entries with no change to the file scope (no reclassification); D = deleted entries; F = frozen entries will be deleted once reclassification of documents from the entries is completed; U = entries that are unchanged.

NOTES:

- **No {curly brackets} are used for titles in CPC only subclasses, e.g. C12Y, A23Y; 2000 series symbol titles of groups found at the end of schemes (orthogonal codes); or the Y section titles. The {curly brackets} are used for 2000 series symbol titles found interspersed throughout the main trunk schemes (breakdown codes).
- U groups: it is obligatory to display the required “anchor” symbol (U group), i.e. the entry immediately preceding a new group or an array of new groups to be created (in case new groups are not clearly subgroups of C-type groups). Always include the symbol, indent level and title of the U group in the table above.
- All entry types should be included in the scheme changes table above for better understanding of the overall scheme change picture. Symbol, indent level, and title are required for all types.
- “Transferred to” column must be completed for all C, D, F, and Q type entries. F groups will be deleted once reclassification is completed.
- When multiple symbols are included in the “Transferred to” column, avoid using ranges of symbols in order to be as precise as possible.
- For administrative transfer of documents, the following text should be used: “< administrative transfer to XX>”, “<administrative transfer to XX and YY simultaneously>”, or “<administrative transfer to XX, YY ...and ZZ simultaneously>” when administrative transfer of the same documents is to more than one place.
- Administrative transfer to main trunk groups is assumed to be the source allocation type, unless otherwise indicated.
- Administrative transfer to 2000/Y series groups is assumed to be “additional information”.
- If needed, instructions for allocation type should be indicated within the angle brackets using the abbreviations “ADD” or “INV”: <administrative transfer to XX ADD> , <administrative transfer to XX INV>, or < administrative transfer to XX ADD, YY INV, ... and ZZ ADD simultaneously>.
- In certain situations, the “D” entries of 2000-series or Y-series groups may not require a destination (“Transferred to”) symbol, however it is required to specify “<no transfer>” in the “Transferred to” column for such cases.
- For finalisation projects, the deleted “F” symbols should have <no transfer> in the “Transferred to” column.
- For more details about the types of scheme change, see CPC Guide.

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B. New, Modified or Deleted Warning(s)

SUBCLASS G01N - INVESTIGATING OR ANALYSING MATERIALS BY DETERMINING THEIR CHEMICAL OR PHYSICAL PROPERTIES (measuring or testing processes other than immunoassay, involving enzymes or microorganisms C12M, C12Q)

<u>Type*</u>	<u>Location</u>	<u>Old Warning</u>	<u>New/Modified Warning</u>
N	G01N 33/54386		Group G01N 33/54386 is impacted by reclassification into groups G01N 33/54387, G01N 33/54388, G01N 33/54389 and G01N 33/54391. All groups listed in this Warning should be considered in order to perform a complete search.
N	G01N 33/54387		Groups G01N 33/54387, G01N 33/54388, G01N 33/54389 and G01N 33/54391 are incomplete pending reclassification of documents from groups G01N 33/54386 and G01N 33/558. All groups listed in this Warning should be considered in order to perform a complete search.
N	G01N 33/558		Group G01N 33/558 is impacted by reclassification into groups G01N 33/54387, G01N 33/54388, G01N 33/54389 and G01N 33/54391. All groups listed in this Warning should be considered in order to perform a complete search.

*N = new warning, M = modified warning, D = deleted warning

NOTE: The "Location" column only requires the symbol PRIOR to the location of the warning. No further directions such as "before" or "after" are required.

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2. A. DEFINITIONS (New)

Insert the following new definitions.

G01N33/54387**Definition statement**

This place covers:

Immunochemical test strips and uses thereof in performing immunochemical assays, in which the test strip contains non-diffusibly immobilised immunochemicals designed to form complexes (with sample analyte or other specific binding partner) in order to analyse a liquid sample flowing through the test strip (typically, membrane or other chromatographic material that supports capillary flow through the strip).

The primary emphasis should be on test strips used to perform immunoassays or other biospecific binding assays. For example, where the overall structure, design, reagents, materials, and/or arrangement of test strip components (e.g. sample zone, reaction zone, analysis zone) are specially adapted for use in a biospecific binding assay.

References**Informative references**

Attention is drawn to the following places, which may be of interest for search:

Using diffusion or migration of antigen or antibody (non-solid phase, i.e. without any non-diffusively bound, permanently immobilised binding partners)	G01N 33/558
Analytical elements (non-immunochemical)	G01N 33/521 – G01N 33/528
Details of handling test elements, e.g. dispensing or storage, not specific to a particular test method	G01N 33/4875
Optical investigation of reagent band	G01N 21/8483, G01N 2021/8488, G01N 2021/8494
Optical investigation of Dipstick/Test strip by observing the effect on a chemical indicator	G01N 2021/7759
Automatic analysis involving test strips	G01N 2035/00108 - G01N 2035/00128
Constructional details of test strips	B01L 2300/0825
Nucleic acid test strip device	C12Q 2565/625

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Special rules of classification

Classification may be made in G01N 33/54387 where the direction of flow is unspecified or where the inventive contribution is indicated to be generally applicable to either vertical or lateral flow, and there is no clearly preferred embodiment.

Classification may also be made here in rare circumstances in which, within a single embodiment, detection complexes are formed directly through a true combination of both vertical and lateral flow. That is, both vertical and lateral flow are used when binding partners are exposed to the non-diffusibly immobilised immunochemicals in detection and/or control zones. This could arise, e.g., if separate detection areas on a single test strip apparatus operate by different flow principles, or if a single detection area receives multiple immunochemicals from both vertical and horizontal directions.

Otherwise, G01N 33/54388 – G01N 33/54391 should be considered.

For lateral flow test strips which may involve some vertical flow of a tangential nature that is not directly involved in formation of the detectable complex on the solid phase (as for example when a sample is applied to a sample receiving pad that is vertically stacked on top of a lateral flow membrane, or a vertically stacked conjugate pad), classification should be made in G01N 33/54388 or G01N 33/54389.

Similarly, where the solid phase detection complex is formed directly as a result of vertical flow, classification should be made in G01N 33/54391 even if there is tangential lateral flow not directly related to complex formation (e.g. sample spreading laterally to saturate the entire surface area before proceeding downwards).

Where the inventive aspects are unrelated to biospecific binding assay applications, and/or for subject matter involving general purpose test strips with only brief suggestion of conventional immunoassay, classification elsewhere should be considered. For example, details of handling test elements, not specific to immunoassay, are best covered in G01N 33/4875.

G01N33/54388

Definition statement

This place covers:

Immunochromatographic test strips and uses thereof, in which a non-diffusibly immobilised immunochemical encounters its corresponding specific binding partner (e.g., analyte or competitor) through lateral flow, i.e. by traversing across the test strip from one side to another.

A lateral flow test strip apparatus may be used in a horizontal orientation or may be used in a vertical orientation (e.g., dipstick-type device).

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A lateral flow test strip apparatus may also involve tangential aspects of vertical flow, as for example when a sample is applied to a sample receiving pad that is vertically stacked on top of a lateral flow membrane, or a vertically stacked conjugate pad. However, a test strip apparatus is still considered to be “based on lateral flow” when a non-diffusibly bound capture moiety comes into contact with its binding partner by lateral flow, i.e. when a detectable complex is formed on the solid phase strip as a consequence of lateral flow.

Special rules of classification

Where a document contains multiple embodiments that are substantially disclosed and supported, one involving lateral flow and one involving vertical flow, then classification may be made in both areas (i.e. G01N 33/54391 and in either G01N 33/54388 or G01N 33/54389 as appropriate). Double classification would not be warranted if the alternative is only briefly suggested, with no exemplification or substantial disclosure.

G01N33/54391

Definition statement

This place covers:

Immunochromatographic test strips and uses thereof, in which a non-diffusibly immobilised immunochemical encounters its corresponding specific binding partner (e.g., analyte or competitor) through vertical flow, e.g. in which the sample moves vertically through a membrane or series of membranes, rather than across a membrane(s) as in a lateral flow assay.

A test strip apparatus is considered to be “based on vertical flow” when a non-diffusibly bound capture moiety comes into contact with its binding partner by vertical flow. Vertical flow test strips may also involve tangential lateral flow (for example, a sample is applied to a central point and spreads laterally to saturate the entire surface area before proceeding downwards), so long as the solid phase detectable complex is formed as a consequence of vertical flow.

“Flow-through” immunochromatographic devices meeting these requirements may be classified here.

Special rules of classification

Where a document contains multiple embodiments that are substantially disclosed and supported, one involving lateral flow and one involving vertical flow, then classification may be made in both areas (i.e. G01N 33/54391 and in either G01N 33/54388 or G01N 33/54389 as appropriate). Double classification would not be warranted if the alternative is only briefly suggested, with no exemplification or substantial disclosure.

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2. A. DEFINITIONS (Modified)

G01N 33/558

Insert: The following two new sections: “Definition statement” and “References, Limiting references”.

Definition statement

This place covers:

Immunoassay/Biospecific binding assay involving diffusion or migration of immunochemicals.

Operable devices, therefore.

References

Limiting references

This place does not cover:

Immunochromatographic test strips	G01N 33/54387
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Special rules of classification

Replace: All of the existing text in the “Special rules of classification” text with the following updated text.

All binding partners are potentially free to diffuse or migrate, i.e., without any non-diffusively bound, permanently immobilised binding partners that are fixed in place throughout the assay. Binding partners could be attached to other diffusible components (e.g. diffusible particulate labels). However, the binding partners are not permanently immobilised in one location throughout the assay but rather are free to diffuse or migrate during at least a part of the assay.

Typically, inventive contribution lies only in the overall structure, design or use of operable devices involving binding reactions featuring one-dimensional flow within a single layer.

Where a binding partner is non-diffusively bound or permanently immobilised in one location throughout the assay, then classification should instead be made in G01N 33/543 or subgroups thereof. For example, immunochromatographic test strips having solid phased binding partners (e.g., capture antibody immobilised in a detection zone) can be classified in G01N 33/54387 – G01N 33/54391.

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3. REVISION CONCORDANCE LIST (RCL)

<u>Type*</u>	<u>From CPC Symbol (existing)</u>	<u>To CPC Symbol(s)</u>
C	G01N 33/54386	G01N 33/54386, G01N 33/54387, G01N 33/54388, G01N 33/54389, G01N 33/54391
C	G01N 33/558	G01N 33/558, G01N 33/54387, G01N 33/54388, G01N 33/54389, G01N 33/54391
D	Y10S 435/96	<administrative transfer to G01N 2474/20>

* C = entries with modified file scope where reclassification of documents from the entries is involved; Q = new entries which are firstly populated with documents via administrative transfers from deleted (D) entries. Afterwards, the transferred documents into the Q entry will either stay or be moved to more appropriate entries, as determined by intellectual reclassification; D = deleted entries; F = frozen entries will be deleted once reclassification of documents from the entries is completed.

NOTES:

- Only C, D, F, and Q type entries are included in the table above.
- When multiple symbols are included in the “To” column, do not use ranges of symbols.
- For administrative transfer of documents, the following text should be used: “< administrative transfer to XX>”, “<administrative transfer to XX and YY simultaneously>”, or “<administrative transfer to XX, YY ...and ZZ simultaneously>” when administrative transfer of the same documents is to more than one place.
- Administrative transfer to main trunk groups is assumed to be the source allocation type, unless otherwise indicated.
- Administrative transfer to 2000/Y series groups is assumed to be “additional information”.
- If needed, instructions for allocation type should be indicated within the angle brackets using the abbreviations “ADD” or “INV”: <administrative transfer to XX ADD>, <administrative transfer to XX INV>, or < administrative transfer to XX ADD, YY INV, ... and ZZ ADD simultaneously>.
- In certain situations, the “D” entries of 2000-series or Y-series groups may not require a destination (“To”) symbol, however it is required to specify “<no transfer>” in the “To” column for such cases.
- RCL is not needed for finalisation projects.

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4. CHANGES TO THE CPC-TO-IPC CONCORDANCE LIST (CICL)

<u>CPC</u>	<u>IPC</u>	<u>Action*</u>
G01N 33/54387	G01N 33/543	NEW
G01N 33/54388	G01N 33/543	NEW
G01N 33/54389	G01N 33/543	NEW
G01N 33/54391	G01N 33/543	NEW
G01N 2470/00	CPCONLY	NEW
G01N 2470/04	CPCONLY	NEW
G01N 2470/06	CPCONLY	NEW
G01N 2470/10	CPCONLY	NEW
G01N 2470/12	CPCONLY	NEW
G01N 2474/00	CPCONLY	NEW
G01N 2474/10	CPCONLY	NEW
G01N 2474/20	CPCONLY	NEW
Y10S 435/96		DELETE

*Action column:

- For an (N) or (Q) entry, provide an IPC symbol and complete the Action column with “NEW.”
- For an existing CPC main trunk entry or indexing entry where the existing IPC symbol needs to be changed, provide an updated IPC symbol and complete the Action column with “UPDATED.”
- For a (D) CPC entry or indexing entry complete the Action column with “DELETE.” IPC symbol does not need to be included in the IPC column.
- For an (N) 2000 series CPC entry which is positioned within the main trunk scheme (breakdown code) provide an IPC symbol and complete the action column with “NEW”.
- For an (N) 2000 series CPC entry positioned at the end of the CPC scheme (orthogonal code), with no IPC equivalent, complete the IPC column with “CPCONLY” and complete the action column with “NEW”.

NOTES:

- F symbols are not included in the CICL table above.
- T and M symbols are not included in the CICL table above unless a change to the existing IPC is desired.