# **C12Q**

MEASURING OR TESTING PROCESSES INVOLVING ENZYMES, NUCLEIC ACIDS OR MICROORGANISMS (immunoassay G01N 33/53); COMPOSITIONS OR TEST PAPERS THEREFOR; PROCESSES OF PREPARING SUCH COMPOSITIONS; CONDITION-RESPONSIVE CONTROL IN MICROBIOLOGICAL OR ENZYMOLOGICAL PROCESSES

#### **Definition statement**

This place covers:

Processes in which there is a direct or indirect qualitative or quantitative measurement or test of a material which contains enzymes, nucleic acids or microorganisms.

Processes in which a material containing enzymes, nucleic acids or microorganisms is used to perform a qualitative or quantitative measurement or test, e.g. testing for antimicrobial activity or cholesterol, geomicrobiological testing.

In vivo or in vitro or in silico measuring or testing processes involving nucleic acid e.g. nucleic acid hybridisation including PCR (Polymerase Chain Reaction).

Compositions or test papers containing enzymes, nucleic acids or microorganisms which can be used to detect or identify a chemical compound or composition, e.g. paper strips for the testing of blood sugar.

Compositions or test papers distinguished by the use of indicators which can be used to detect or identify the presence of enzymes, nucleic acids or microorganisms.

Processes of making such test compositions.

Processes involving enzymes or microorganisms in which a process parameter is measured and that or another process parameter is varied in response to such measurement, i.e. condition responsive control.

## Relationships with other classification places

Controlling or regulating in general is classified in <u>G05</u>.

The codes of subclass <u>C12R</u> are only for use as Indexing codes associated with subclasses <u>C12C</u> - <u>C12Q</u>, so as to provide information concerning the microorganisms used in the processes classified in these subclasses.

#### References

## Limiting references

This place does not cover:

Immunoassay	G01N 33/53
Immunoassay with enzyme label	G01N 33/535
Immunoassay with the carrier being a biological cell or cell fragment	G01N 33/554
Immunoassay for microorganisms	G01N 33/569
Immunoassay for venereal diseases	G01N 33/571
Immunoassay for enzymes and isoenzymes	G01N 33/573
Immunoassay for cancer	G01N 33/574

Immunoassay for hepatitis	G01N 33/576
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#### Informative references

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

Microorganisms per se	C12N 1/00
Human, animal or plant cells per se	C12N 5/00
Viruses per se	C12N 7/00
Enzymes per se	C12N 9/00, C12N 11/00
Investigating or analysing materials by determining their chemical or physical properties	<u>G01N</u>
Chemical analysis involving blood sugar, e.g. galactose	G01N 33/66
Chemical analysis involving proteins, peptides and amino acids	G01N 33/68
Chemical analysis involving lipids, e.g. cholesterol	G01N 33/92

## Special rules of classification

In this subclass, in absence of an indication to the contrary, classification is made in the last appropriate place.

In this subclass, test media are classified in the appropriate group for the relevant test process.

In this subclass, bacteria, fungi, viruses, protozoa and algae are considered as microorganisms.

In this subclass, sub-cellular parts, unless specifically provided for, are classified with the whole cell.

## **Combination Sets [C-Sets]:**

In this subclass, C-Sets classification is applied to the following groups, listed in the table below, if the document discloses a pertinent combination of technical features that cannot be covered by the allocation of a single symbol. The fourth column of the table indicates the place where the detailed information about the C-Sets construction and the associated syntax rules can be found, in the definition section "Special rules of classification".

C-SETS ID	BASE SYMBOL	SUBSEQUENT SYMBOLS	C-SETS FORMULA; LOCATION OF C-SETS RULES
#C12Qa	C12Q 1/68 - C12Q 1/6874, C12Q 1/6897, C12Q 1/70	C12Q 2500/00 - C12Q 2565/634	(C12Q, C12Q); measuring or testing processes involving in a nucleic acid; see C12Q 1/68
#C12Na	C12N 15/10 - C12N 15/1096	C12Q 2500/00 - C12Q 2565/634	(C12N, C12Q); DNA or RNA isolation/preparation process and cell culture components; see C12N 15/10
#C12Nb	C12N 15/64 - C12N 15/66	C12Q 2500/00 - C12Q 2565/634	(C12N, C12Q); general methods for preparing vectors; see C12N 15/64

The specific C-Sets rule is located at only one place of the base symbol in the section "Special rules of classification" in the definition. If the C-Sets rule is applicable to all groups of a subclass, it is located

at the subclass level only. If the same C-Sets rule is applicable to multiple groups or subgroups within the same subclass, the C-Sets rule is placed at the highest group or subgroup of the multiple groups.

## **Glossary of terms**

In this place, the following terms or expressions are used with the meaning indicated:

Enzyme	Proteinaceous material which causes a chemical change in a starting material without being consumed in the reaction.
Involving	When used in relation to a substance, includes the testing for the substance as well as employing the substance as a determinant or reactant in a test for a different substance.
Microorganism	For the purposes of classification, this term includes bacteria, fungi, viruses, protozoa and algae.
Nucleic acid	Comprises nucleic acids as in vitro compounds as well as subcellular parts in vivo like chromosome territories within the nucleus, plasmids, gene sequences, genetic information, mutations, polymorphisms such as SNPs, in silico base sequences, aptamers (ligand binding nucleic acids) and ribozymes (catalytic active RNA molecules).

## C12Q 1/00

Measuring or testing processes involving enzymes, nucleic acids or microorganisms (measuring or testing apparatus with condition measuring or sensing means, e.g. colony counters, <u>C12M 1/34</u>); Compositions therefor; Processes of preparing such compositions

#### **Definition statement**

This place covers:

Processes in which there is a direct or indirect qualitative or quantitative measurement or test of a material which contains enzymes, nucleic acids or microorganisms.

Processes in which a material containing enzymes, nucleic acids or microorganisms is used to perform a qualitative or quantitative measurement or test, e.g. testing for antimicrobial activity or cholesterol, geomicrobiological testing.

In vivo or in vitro or in silico measuring or testing processes involving nucleic acid e.g. nucleic acid hybridisation including Polymerase Chain Reaction [PCR]. See section range <a href="C12Q 1/708">C12Q 1/708</a>.

Compositions or test papers containing enzymes, nucleic acids or microorganisms which can be used to detect or identify a chemical compound or composition, e.g. paper strips for the testing of blood sugar.

Compositions or test papers distinguished by the use of indicators which can be used to detect or identify the presence of enzymes, nucleic acids or microorganisms.

Processes of making such test compositions.

### References

#### Limiting references

This place does not cover:

Measuring or testing apparatus with condition measuring or sensing	C12M 1/34
means, e.g. colony counters	

#### Informative references

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

Apparatus for condition-responsive control processes	C12M 1/36
Microorganisms per se	C12N 1/00
Human, animal or plant cells per se	C12N 5/00
Viruses per se	C12N 7/00
Enzymes per se	C12N 9/00, C12N 11/00
Investigating or analysing materials by determining their chemical or physical properties	<u>G01N</u>
Observation of the progress or of the result of processes specified in this group by any of the methods specified in groups G01N 3/00 - G01N 29/00	<u>G01N</u>
Investigating or analysing biological material	G01N 33/48- G01N 33/98
Testing involving plant cells	G01N 33/5097
Immunoassay for plant cells	G01N 33/56961
Immunoassay for animal cells	G01N 33/56966
Chemical analysis involving blood sugar, e.g. galactose	G01N 33/66
Chemical analysis involving proteins, peptides and amino acids	G01N 33/68
Chemical analysis involving lipids, e.g. cholesterol	G01N 33/92

## Special rules of classification

In this group, test media are classified in the appropriate group for the relevant test process.

Classification in main group C12Q 1/00 and sub-groups C12Q 1/001 - C12Q 1/66 is further refined using Indexing Codes from the range C12Q 2304/00 - C12Q 2337/52. The definitions and scope of these Indexing Codes are self evident. The codes and definitions are listed at the end of this document.

Due to the strong relationship between the range  $\underline{\text{C12Q 1/00}}$  -  $\underline{\text{C12Q 1/66}}$  and the range  $\underline{\text{G01N 33/50}}$  -  $\underline{\text{G01N 33/98}}$ , "Chemical analysis of biological material", and the rather broad nature of the definitions of some of the  $\underline{\text{C12Q 1/001}}$  -  $\underline{\text{C12Q 1/66}}$  sub-groups, refinement of the classification in this area by allocation of Indexing Codes from the range  $\underline{\text{G01N 2333/00}}$  -  $\underline{\text{G01N 2800/60}}$ , where possible, is considered mandatory.

Observation of the progress or of the result of processes specified in this group by any of the methods specified in groups  $\underline{\text{G01N 3/00}}$  -  $\underline{\text{G01N 29/00}}$  may require additional classification in these groups.

# {Enzyme electrodes}

#### **Definition statement**

This place covers:

Enzyme-based Electrochemical sensors where inventive concept lies in the enzyme aspect e.g. enzyme used, how attached to electrode, enzyme mediator involvement, enzyme sensing mechanism/ system.

#### References

#### Informative references

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

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

Apparatus specifically adapted for solid-phase testing in biospecific ligand binding assays or immunological testing/immunoassays	G01N 33/54366
Involving physiochemical end-point determination	G01N 33/54373
Electrodes	<u>G01N 33/5438</u> .

## C12Q 1/002

# {Electrode membranes}

### **Definition statement**

This place covers:

Enzyme electrodes where inventive concept lies in the use of or construction of a membrane on or in which an enzyme or multi-enzyme sensing system is attached or entrapped

## **Glossary of terms**

In this place, the following terms or expressions are used with the meaning indicated:

Membrane	Any non-conductive porous structure
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## C12Q 1/003

## {Functionalisation}

## **Definition statement**

This place covers:

Inventive concept lies in chemical e.g. silylation or physical e.g. plasma treatment of the electrode membrane to alter/create functional groups for attachment of enzyme. May also include crosslinking or other treatments of membrane polymers. Overlap with <a href="https://gold.ncbi.org/gold.ncbi.nlm.ncbi.org/gold.ncbi.org/

## Relationships with other classification places

Chemical functionalisation of solid-phases for ligand attachment for use in biospecific ligand binding assays or immunological testing/immunoassays <u>G01N 33/54353</u>.

Relationships with other classification places

With the ligand physically entrapped within the solid phase G01N 33/5436.

Treatment of solid-phases (e.g. coating, irradiation) for the purpose of improving reaction conditions (e.g. reduction of non-specific binding, promotion of specific binding <u>G01N 33/54393</u>.

## C12Q 1/004

## {mediator-assisted}

#### **Definition statement**

This place covers:

Enzyme electrodes where the enzyme or multi-enzyme sensing system requires a mediator e.g. cofactors (NAD/FAD), ferrodoxins.

## C12Q 1/005

{involving specific analytes or enzymes (including groups of enzymes, e.g. oxydases; C12Q 1/004 takes precedence)}

#### **Definition statement**

This place covers:

Enzyme electrodes directed to analysis of specific molecules or use of specific enzymes. Use of multi-enzyme systems such as oxido-reductase systems may also be classified in <a href="C12Q 1/004">C12Q 1/004</a> if the mediator is of importance.

## C12Q 1/006

## {for glucose}

#### **Definition statement**

This place covers:

Enzyme electrodes specifically designed for the analysis of glucose.

#### C12Q 1/007

# {involving isoenzyme profiles (for detection of an individual isoenzyme C12Q 1/25 - C12Q 1/66)}

## **Definition statement**

This place covers:

Methods for determining isoenzyme profiles. Overlap with G01N 33/573, G01N 33/5735.

## References

## Informative references

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

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

Biospecific ligand binding assays or immunological testing/immunoassays	G01N 33/573
for isoenzymes	

# {for determining co-enzymes or co-factors, e.g. NAD, ATP}

#### **Definition statement**

This place covers:

Methods for detecting, measuring or identifying co-enzymes or co-factors e.g. NAD, ATP involved in enzyme reactions.

## References

#### Informative references

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

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

Biospecific ligand binding assays or immunological testing/immunoassays	G01N 33/5735
for co-enzymes or co-factors	

## C12Q 1/02

# involving viable microorganisms

#### **Definition statement**

This place covers:

Methods or processes for living microorganisms which cannot be classified elsewhere in <a href="C12Q 1/00">C12Q 1/00</a>. Includes Total Viable Organism (TVO) testing and electrophysical measurements such as ion channel current.

C12Q 1/02 and subgroups includes testing for microorganisms where the desired result indicates non-viability.

### References

## Limiting references

This place does not cover:

Specific binding assays/Immunoassays for microorganisms are classified in	G01N 33/569 - G01N 33/571
For hepatitis	G01N 33/576

## C12Q 1/025

{for testing or evaluating the effect of chemical or biological compounds, e.g. drugs, cosmetics (antimicrobial activity C12Q 1/18)}

#### **Definition statement**

This place covers:

Methods or processes for testing or evaluating non antimicrobial chemical or biological compounds such as drugs, cosmetics.

### References

#### Limiting references

This place does not cover:

Antimicrobial activity	C12Q 1/18
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#### Informative references

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

Testing or evaluating the effect of chemical or biological compounds, e.g. drugs, cosmetics, using animal cells	G01N 33/5008
Testing or evaluating the effect of chemical or biological compounds, e.g. drugs, cosmetics, using plant cells	G01N 33/5097

## C12Q 1/04

Determining presence or kind of microorganism; Use of selective media for testing antibiotics or bacteriocides; Compositions containing a chemical indicator therefor {(C12Q 1/6897 takes precedence)}

#### **Definition statement**

This place covers:

Methods or processes (qualitative testing) designed to determine the presence or identity (variety, species, genus or Gram +/-) of a microorganism, including compositions containing an indicator for presence or identity of a microorganism.

## C12Q 1/045

## {Culture media therefor}

## **Definition statement**

This place covers:

Methods, processes or compositions wherein the inventive concept lies in the composition or content of the culture media e.g. percentage ratio of components, compounds present in medium itself (carbon source, nitrogen source, vitamins etc.)

## C12Q 1/06

#### Quantitative determination

#### **Definition statement**

This place covers:

Methods and processes (quantitative testing) for numerical counting the number of viable microorganisms or viable/non-viable ratio in a sample.

## using multifield media

#### **Definition statement**

This place covers:

Methods, processes or compositions involving use of a multifield media (single media permitting identification of multiple results or single item e.g. petri dish comprising more than one medium to allow multiple results) in methods and processes (quantitative testing) for numerical counting the number of viable microorganisms or viable/non-viable ratio in a sample.

## C12Q 1/10

#### Enterobacteria

#### **Definition statement**

This place covers:

Methods, processes or compositions involving quantitative determination of Enterobacteria e.g. Citrobacter, Serratia, Proteus, Providencia, Morganella, Yesinia, Escherichia, Shigella, Salmonella, Klebsiella, Enterobacter, Erwinia, Hafnia.

#### C12Q 1/12

## Nitrate to nitrite reducing bacteria

## **Definition statement**

This place covers:

Methods, processes or compositions involving quantitative determination of bacteria under nitrate to nitrite reducing conditions. Some bacteria e.g. E.Coli use nitrate under anaerobic growth conditions.

## C12Q 1/14

#### Streptococcus; Staphylococcus

## **Definition statement**

This place covers:

Methods, processes or compositions involving quantitative determination of Streptococcus or Staphylococcus bacteria.

## C12Q 1/16

#### using radioactive material

## **Definition statement**

This place covers:

Methods, processes or compositions for detecting presence or kind of microorganism (qualitative testing) designed to determine the presence or identity (variety, species, genus or Gram +/-) of a microorganism. wherein the inventive concept lies in the use of radioisotopes (e.g. 11C, 13 C, 14C, 2H, 3H, 15N, 35S, 35P).

## Testing for antimicrobial activity of a material

#### **Definition statement**

This place covers:

Methods or processes for testing of antimicrobial activity of a compound on living microorganisms.

## C12Q 1/20

# using multifield media

#### **Definition statement**

This place covers:

Methods, processes or compositions involving the use of a multifield media (single media permitting identification of multiple results or single item e.g. petri dish comprising more than one medium to allow multiple results) in methods or processes for testing of antimicrobial activity of a compound on living microorganisms.

## C12Q 1/22

## **Testing for sterility conditions**

## **Definition statement**

This place covers:

Methods or processes for testing if sterility conditions have been achieved or are being maintained. Examples are labels for food packaging, testing of medical instrument sterilization methods, air or water quality.

## Special rules of classification

In the following sub-groups C12Q1/25 - C12Q1/66 classification is based on the Enzyme Nomenclature as the IUB internationally agreed method.

## C12Q 1/24

# Methods of sampling, or inoculating or spreading a sample; Methods of physically isolating an intact microorganisms

#### **Definition statement**

This place covers:

Methods for sampling/physically isolating intact microorganisms (including non-viable microorganisms) are classified in C12Q 1/24 irrespective of what becomes of them afterwards. If the isolated microorganisms are further subject to immunoassay/biospecific binding assay a further symbol from G01N 33/569 or subgroups would be added.

## involving enzymes not classifiable in groups C12Q 1/26 (- C12Q 1/66)

#### **Definition statement**

This place covers:

Methods, processes or compositions involving enzymes having unidentifiable EC number and enzymes which cannot be classified elsewhere in C12Q 1/26-C12Q 1/66. Classified under this symbol are methods, processes or compositions involving enzymes classified EC 6.X.X.X. These enzymes are characterised by bond formation C-O (6.1), C-S (6.2), C-N (6.3), C-C (6.4), P-O (.5), N-Met (6.6) and may commonly be known as ligase, synthase, carboxylase, cyclase, chelatase.

#### C12Q 1/26

## involving oxidoreductase

#### **Definition statement**

This place covers:

Methods, processes or compositions involving enzymes classified as EC 1.X.X.X oxidoreductases, not comprising as part of the IUB name 'dehydrogenase' (see C12Q 1/32) and which cannot be classified elsewhere in C12Q 1/26-C12Q 1/32. Enzymes are characterised by the catalysis of oxidation/reduction reactions and may comprise as part of their IUB name reductase, oxidase, synthase, dismutase, hydrogenase, oxygenase

## C12Q 1/28

#### involving peroxidase

## **Definition statement**

This place covers:

Methods, processes or compositions involving peroxidase enzymes classified EC 1.11.1.X including peroxidase enzyme itself (EC 1.11.1.7).

## C12Q 1/30

## involving catalase

## **Definition statement**

This place covers:

Methods, processes or compositions involving catalase enzyme, EC 1.11.1.6.

## C12Q 1/32

## involving dehydrogenase

#### **Definition statement**

This place covers:

Methods, processes or compositions involving enzymes having an EC number 1.X.X.X and which contain 'dehydrogenase' in the IUB standard enzyme name.

## involving hydrolase

#### **Definition statement**

This place covers:

Methods, processes or compositions involving enzymes classified as EC 3.X.X.X hydrolases and which cannot be classified elsewhere in C12Q 1/37-C12Q 1/46. Enzymes are characterised by the catalysis of the addition or removal of a water molecule and may comprise as part of their IUB name hydrolase, lipase, lactonase, nuclease, nucleotidase, NTPase, helicase, amidase, sulfatase, depolymerase, glycosylase and variants e.g. ribonuclease. Methods, processes or compositions involving urease (EC 3.5.1.5) - C12Q 1/58. Methods, processes or compositions involving (phospho)lipase - C12Q 1/61.

#### C12Q 1/37

## involving peptidase or proteinase

#### **Definition statement**

This place covers:

Methods, processes or compositions involving enzymes classified as EC 3.4.X.X. The enzymes are classified as acting on peptide bonds and may comprise as part of the IUB name peptidase and variants e.g. dipeptidase, aminopeptidase. Methods, processes or compositions involving clotting factors - C12Q 1/56.

There are many enzymes classified in the area EC 3.4.21.X - 3.4.23.X which retain the 'original' names e.g. trypsin, complement factors, kallikrein, subtilisin, papain, Meprin A, renin.

## C12Q 1/40

## involving amylase

## **Definition statement**

This place covers:

Methods, processes or compositions involving enzymes classified as EC 3.2.1.X. Enzymes are characterised by hydrolysis of O - and S -glycosyl compounds and may comprise as part of the IUB name (sugar residue)sidase e.g. galactosidase, mannosidase.

There are many enzymes classified in the area EC 3.2.1.X which retain the 'original' names e.g. amylase, lysozyme, lactase.

## C12Q 1/42

## involving phosphatase

## **Definition statement**

This place covers:

Methods, processes or compositions involving enzymes classified as EC 3.1.3.X. Enzymes are characterised by hydrolysis of phosphoric monoesters and usually comprise as part of the IUB name phosphatase.

## involving esterase

#### **Definition statement**

This place covers:

Methods, processes or compositions involving enzymes classified as EC 3.1.X.X having as part of the IUB name 'esterase' or variant e.g. diesterase, thioesterase. Enzymes are characterised by acting on ester bonds.

## C12Q 1/46

## involving cholinesterase

#### **Definition statement**

This place covers:

Methods, processes or compositions involving acetylcholinesterase, EC 3.1.1.7 or cholinesterase EC 3.1.1.8.

## C12Q 1/48

# involving transferase

## **Definition statement**

This place covers:

Methods, processes or compositions involving enzymes classified as EC 2.X.X.X transferases and which cannot be classified elsewhere in C12Q 1/485-C12Q 1/52. Enzymes are characterised by the transfer of a functional group and may comprise as part of their IUB name kinase, transferase, synthase, phosphorylase and variants e.g. aminotransferase.

## C12Q 1/485

## {involving kinase}

## **Definition statement**

This place covers:

Methods, processes or compositions involving enzymes classified as EC 2.7.X.X having as part of the IUB name 'kinase' or variant. Enzymes are characterised by the transfer of phosphorus-containing groups.

# C12Q 1/50

# involving creatine phosphokinase

# **Definition statement**

This place covers:

Methods, processes or compositions involving enzyme creatine (phospho)kinase, EC 2.7.3.2.

## involving transaminase

#### **Definition statement**

This place covers:

Methods, processes or compositions involving enzymes classified as EC 2.6.1.X and may comprise as part of the IUB name 'transaminase'. Enzymes are characterised by the transfer of nitrogenous groups.

## C12Q 1/527

## involving lyase

#### **Definition statement**

This place covers:

Methods, processes or compositions involving enzymes classified as EC 4.X.X.X lyases and may comprise as part of the IUB name lyase, carboxylase, aldolase, hydratase and variants e.g. decarboxylase, dehydratase. Enzymes are characterised by the catalysis of reactions involving the formation of or addition to a double bond.

## C12Q 1/533

## involving isomerase

#### **Definition statement**

This place covers:

Methods, processes or compositions involving enzymes classified as EC 5.X.X.X isomerases and may comprise as part of the IUB name racemase, mutase, epimerase, isomerase, tautomerase, synthase and variants e.g. aminomutase. Enzymes are characterised by the catalysis of isomerisation reactions.

#### Special rules of classification

The sub-groups <u>C12Q 1/54</u> - <u>C12Q 1/66</u> are intended to highlight specific subject-matter which might also take an earlier symbol. The sub-groups <u>C12Q 1/54</u> - <u>C12Q 1/66</u> take precedence over earlier sub-groups under the Last Place Rule.

## C12Q 1/54

## involving glucose or galactose

## **Definition statement**

This place covers:

Methods, processes or compositions involving glucose or galactose where glucose or galactose are the final analyte or subject of the test e.g. diabetes testing, glucose demand for testing presence of microorganisms, Glucose Tolerance Test, use of glucose or galactose in the production of enzymes. Electrochemical glucose sensors where the inventive concept is in an electrode or other sensor structure to specifically enhance glucose determinations are classified in C12Q 1/006.

# involving blood clotting factors, e.g. involving thrombin, thromboplastin, fibrinogen

#### **Definition statement**

This place covers:

Methods, processes or compositions involving blood clotting factors e.g. thrombin, fibrinogen, thromboplastin. Includes investigation and/or identification of compounds which are present in or modulate the clotting pathway.

## C12Q 1/58

## involving urea or urease

#### **Definition statement**

This place covers:

Methods, processes or compositions involving detection of urea or urease (EC 3.5.1.5). Includes measurement of Biological Nitrogen Demand. Urea electrodes where the inventive concept is in the electrode are classified in C12Q 1/001 - C12Q 1/005. Includes detection of ammonia.

#### C12Q 1/60

## involving cholesterol

## **Definition statement**

This place covers:

Methods, processes or compositions involving detection of cholesterol or LDL-cholesterol. Cholesterol electrodes where the inventive concept is in the electrode are classified in <a href="C12Q 1/005">C12Q 1/005</a>.

## Relationships with other classification places

Overlap with G01N 33/92.

## C12Q 1/61

## involving triglycerides

#### **Definition statement**

This place covers:

Methods, processes or compositions involving detection of triglycerides, e.g. as biomarkers for disease, HDL, LDL, CM values or acting as substrate for determination of (phospho)lipase enzymes.

## Relationships with other classification places

Overlap with G01N 33/92.

## involving uric acid

#### **Definition statement**

This place covers:

Methods, processes or compositions involving detection of uric acid, often using the enzyme uricase (EC 1.7.3.3). Includes detection of uric acid as breakdown product indicative of other analytes e.g. purine bases, nucleotides.

## C12Q 1/64

## Geomicrobiological testing, e.g. for petroleum

#### **Definition statement**

This place covers:

Methods, processes or compositions involving detection of microbiological degradation or contamination of in-situ hydrocarbon reserves, hydrocarbon reserve prospecting using microorganisms, monitoring of microorganism contamination of liquid hydrocarbon fuels, carbon dioxide sequestering by subterranean microorganism methane production.

## C12Q 1/66

## involving luciferase

#### **Definition statement**

This place covers:

Methods, processes or compositions involving luciferase (EC 1.13.12.X or EC 1.14.14.3).

## C12Q 1/68

## involving nucleic acids

## **Definition statement**

This place covers:

All documents which cannot be classified in any of the other groups but relate to the enzymatic manipulation of nucleic acids.

## Relationships with other classification places

Group C12Q 1/00 relates to enzymes. From group C12Q 1/68 onwards, assays and products for analysing or detecting nucleic acids are covered irrespective of whether enzymes or microorganisms are involved. Group C12Q 1/70 similarly relates to nucleic acid assays and products for analysing or detecting viruses or bacteriophages.

Nucleic acid amplification reactions are classified in group C12P 19/34 if the focus of the subject-matter is on the enzymes or the enzyme modifications per se. However, if the enzyme modification results in a changed/improved analytical effect, classification is also effected in group C12Q 1/68.

# References

## Informative references

Immunization, vaccines	A61K 39/00
Viral antigens in a vaccine	A61K 39/12
Gene therapy	A61K 48/00
Design and fabrication of microarrays (biochips) wherein the invention resides in the synthesis of polypeptides or polynucleotides; Apparatus and devices for combinatorial chemistry or for making molecular arrays.	B01J 19/0046
Microfluidic systems used for nucleic acid analysis like thermal cyclers (PCR-machines), capillary sequencers	B01L 1/00- B01L 99/00
Chemical synthesis or modification of nucleosides, nucleotides or oligonucleotides (chemically linked to other compounds, fluorescent labels).	C07H 21/00- C07H 21/04
Bacterial, fungal, protozoal, vertebrate antigens.	C07K 14/00 - C07K 14/825
Antibodies	C07K 16/00
Undifferentiated human, animal or plant cells	C12N 5/00
Plant cells	C12N 5/04
Animal cells	C12N 5/06
Cells modified by introduction of foreign genetic material	C12N 5/10
Viruses; Bacteriophages	C12N 7/00
Bacterial, fungal and protozoan enzymes	C12N 9/00
Extraction and purification of nucleic acids from biological samples, e.g. pure separation or isolation methods; Conditions, buffers or apparatuses therefore	C12N 15/10
Isolating individual clones by screening libraries; making libraries	C12N 15/1034 - C12N 15/1093
DNA or RNA fragments; Modified forms thereof	C12N 15/11
Introduction of foreign genetic material using vectors; Vectors; Use of hosts therefor; Regulation of expression	C12N 15/63
Bacterial vectors	C12N 15/70 -C12N 15/78
Vectors for fungal cells	<u>C12N 15/80</u> - <u>C12N 15/815</u>
Introduction of foreign genetic material using processes not otherwise provided for, e.g. co-transformation	C12N 15/8201- C12N 15/8214
Animal vectors and their preparation	C12N 15/85
Sensors and electronic devices involving nucleic acids wherein the electrical detection is important	G01N 27/00, G01N 31/00
Sensors and electronic devices wherein the optical detection is important	G01N 31/00
Protein diagnostics and detection	G01N 33/68
Coulter counters	G01N 35/00- G01N 35/1097
Computer systems using nucleic acids	G11C 13/0019

Informative references

Bioinformatics	<u>G16B</u>
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# Special rules of classification

In groups C12Q 1/68 - C12Q 1/708, the common rule is applied, i.e. the classification is made at the most appropriate place.

#### Classification guidance

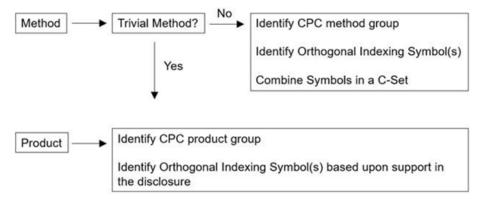
The subgroups C12Q 1/68 - C12Q 1/708 are divided in method groups and nucleic acid product groups (primers, probes, arrays, and other nucleic acid products) as shown in the tables below.

Depending on which kind of subject matter of invention is being classified (i.e. method or product), different rules for classification apply.

If the methods disclosed by an application are known or trivial, classification of such trivial methods is determined based on the use of the products identified and follows the classification guidance for products.

Orthogonal Indexing symbols C12Q 2500/00 - C12Q 2565/634 are used with the CPC method groups.

Orthogonal Indexing symbols of the groups  $\underline{\text{C12Q }2600/00}$  -  $\underline{\text{C12Q }2600/178}$  are used with the CPC product groups.



## Classification of Nucleic acid product groups and trivial methods:

Nucleic acid product groups are shown below:

Symbol	Title
C12Q 1/6876	Hybridisation probes, primers, and other nucleic acid products
C12Q 1/6879	For sex determination
C12Q 1/6881	For tissue and cell typing, e.g. hla probes
C12Q 1/6883	For diseases caused by alterations of genetic material
C12Q 1/6886	For cancer
C12Q 1/6888	For detection or identification of organisms
C12Q 1/689	For bacteria
C12Q 1/6893	For protozoa
C12Q 1/6895	For plants, fungi, or algae
C12Q 1/701	Specific hybridisation probes

C12Q 1/702	For retroviruses
C12Q 1/703	Viruses associated with AIDS
C12Q 1/705	For herpetoviridae, e.g. herpes simplex, varicella zoster
C12Q 1/706	For hepatitis
C12Q 1/707	Non-A, non-B Hepatitis, excluding hepatitis D
C12Q 1/708	For papilloma

Classification guidance for nucleic acid products and trivial methods:

- The nucleic acid product groups <u>C12Q 1/6876</u> <u>C12Q 1/6895</u> and <u>C12Q 1/701</u> <u>C12Q 1/708</u> are allocated as single symbols in conjunction with orthogonal Indexing symbols of the groups <u>C12Q 2600/00</u> <u>C12Q 2600/178</u>.
- The C12Q 2600/00 orthogonal Indexing symbols are given as independent symbols.
- The use of the <a href="C12Q 2600/00">C12Q 2600/00</a> codes is compulsory. They should be given if the claims and/or examples support a functional use as given by any of the <a href="C12Q 2600/00">C12Q 2600/00</a> symbols as shown above.

#### **Examples for nucleic acid product groups:**

Example 1. An invention is directed to the identification of the TNF haplotype TNF-1031C/-857C/-863C/-308G and its association with Crohn's Disease. The disclosure provides data showing a significant association of the haplotype with the Crohn's Disease. The invention also relates to the identification of the -857C allele. The methods and means for determining these polymorphisms and haplotypes are known in the art, therefore considered as trivial.

The nucleic acid product symbol for this invention is C12Q 1/6883.

Although the method for determining the -857C polymorphism is known, adding the orthogonal indexing symbol C12Q 2600/156 (polymorphic or mutational markers) will help in retrieving the information about use of the identified polymorphic allele, like 857C, and its association with Crohn's Disease.

The method for determining the haplotype is known. However, adding the orthogonal indexing symbol C12Q 2600/172 (Haplotypes) will aid in retrieving the information about use of haplotypes, like TNF-1031C/-857C/-863C/-308G, and its association with Crohn's Disease.

The complete classification should therefore be C12Q 1/6883, C12Q 2600/156 and C12Q 2600/172.

Example 2. An application relates to the use of the B1153 gene in testing for an allergic disease. The expression level of this gene is increased in patients with an allergic disease. The methods and means for determining the expression level are trivial.

The nucleic acid product symbol for this application is <a>C12Q</a> <a>1/6883</a>.

The methods for determining the expression level are trivial but adding the orthogonal indexing symbol C12Q 2600/158 (expression marker) will aid in retrieving the information of use of specific expression markers, including B1153.

The complete classification should therefore be C12Q 1/6883 and C12Q 2600/158.

Example 3. An application relates to the use of a SNP for determining if a patient would benefit from an anti-cancer therapy. The methods and means for determining the SNP are trivial.

The nucleic acid product symbol for this application would be C12Q 1/6886.

The methods for determining the SNP are trivial but adding the orthogonal indexing symbol C12Q 2600/156 (polymorphic or mutational markers) will aid in retrieving information about polymorphic or mutational markers.

In addition, the application claims pharmacogenomics. If the application provides evidence-based support (e.g. examples) for this claim, orthogonal indexing symbol <a href="C12Q 2600/106">C12Q 2600/106</a> is also given. If no support is present, only the Indexing symbol for polymorphic marker C12Q 2600/156 is given.

The complete classification should therefore be:

- C12Q 1/6886 and C12Q 2600/156 if no support is present, or
- C12Q 1/6886, C12Q 2600/106 and C12Q 2600/156 if the application provides support for a pharmacogenomics claim.

## Classification of non-invention information (additional information):

All subgroups in C12Q 1/68 - C12Q 1/708 can be used for classifying non-invention information (or Additional information) that compliments Invention information and is useful for searches. Such Additional information is given under the classifier's discretion. The following example illustrates how to classify non-invention information as (A) that is useful for search:

Example: An application relates to oligonucleotide probes used for the species-specific identification of parodontophathogenic bacteria by in situ hybridisation. The methods for performing the in situ hybridisation are known in the art and considered as non-invention.

The application is given C12Q 1/689 for the bacterial detection probes as Inventive information.

Although the method in situ hybridisation is known in the art, adding <u>C12Q 1/6841</u> (in situ hybridisation) as Additional information will aid in retrieving the method of identifying novel bacteria by using in situ hybridisation.

In searching, the combination of <u>C12Q 1/689</u> (Inventive information (I)), <u>C12Q 1/6841</u>(Additional information (A)), and keywords will directly lead to the most relevant documents.

The complete classification should therefore be:

- C12Q 1/689 (I)
- C12Q 1/6841(A)

#### Classification of methods groups as invention information:

Within <u>C12Q 1/68</u> - <u>C12Q 1/6874</u> and <u>C12Q 1/6897</u> - <u>C12Q 1/70</u>, the following subgroups listed in table below are considered as method groups related to nucleic acids.

Symbol	Title
C12Q 1/6804	Nucleic acid analysis utilising immunogens
C12Q 1/6806	Preparing nucleic acids for analysis, e.g. for PCR assay
C12Q 1/6809	Sequence identification involving differential detection
C12Q 1/6811	Selection methods for production or design of target specific oligonucleotide or binding molecules
C12Q 1/6813	Hybridisation assays
C12Q 1/6816	Characterised by the means of detection
C12Q 1/6818	Involving interaction of at least two labels, e.g. resonant energy transfer
C12Q 1/682	Signal amplification

C12Q 1/6823	Release of bound marker
C12Q 1/6825	Nucleic acid detection involving sensors
C12Q 1/6827	For mutation or polymorphism detection
C12Q 1/683	Involving restriction enzymes, e.g. rflp
C12Q 1/6832	Enhancement of hybridisation reaction
C12Q 1/6834	Nucleic acid analysis involving immobilisation; Immobilisation characterised by the carrier or coupling agent
C12Q 1/6837	Characterised by the use of probe arrays or probe chips
C12Q 1/6839	Triple helix formation in hybridisation assays
C12Q 1/6841	In situ hybridisation
C12Q 1/6844	Nucleic acid amplification reactions
C12Q 1/6846	Common amplification features
C12Q 1/6848	Preventing contamination
C12Q 1/6851	Quantitative amplification
C12Q 1/6853	Using modified primers or templates
C12Q 1/6855	Ligating adaptors
C12Q 1/6858	Allele specific amplification
C12Q 1/686	Polymerase chain reaction [PCR]
C12Q 1/6862	Ligase chain reaction [LCR]
C12Q 1/6865	Promoter based amplification, e.g. NASBA, 3SR, TAS
C12Q 1/6867	Replicase based amplifications, e.g. Q-beta replicase
C12Q 1/6869	Methods for sequencing; sequencing using nanopores and other sequencing systems based on physical properties of nucleic acids, e.g. Atomic Force Microscopy [AFM]
C12Q 1/6872	Involving mass spectrometry
C12Q 1/6874	Involving nucleic acid arrays, e.g. sequencing by hybridisation [SBH]
C12Q 1/6897	Involving reporter genes operably linked to promoters
C12Q 1/70	Involving viruses and Bacteriophages

## Combination sets (C-Sets):

Methods related to nucleic acids as listed above in the table are classified in the form of C-Sets, which follows C-Sets rule #C12Qa as described in below.

#### C-Sets statement: #C12Qa

• In these C-Sets, the base symbol, representing the type of method are taken from the groups C12Q 1/68 - C12Q 1/6874, C12Q 1/6897 and C12Q 1/70, whereas the subsequent symbols representing the essential technical features of the method are taken from the orthogonal symbols C12Q 2500/00 - C12Q 2565/634.

- Orthogonal symbols <u>C12Q 2500/00</u> <u>C12Q 2565/634</u> are only used as subsequent symbols in C-Sets and should not be allocated as single symbol.
- In the C-Set, only the essential technical features of the invention, which differentiate it from the prior art, are to be represented: only exceptionally more than three technical feature (orthogonal symbols) codes should make up the C-Set. The least possible number of orthogonal symbols should be included in the C-Set.
- All indexing codes from groups <u>C12Q 2500/00</u> <u>C12Q 2565/634</u> are to be used in the context
  literally expressed in the phrase ascribed to the code, i.e. the use of an indexing code is neither
  restricted by its hierarchical position in a group nor by the definition of the group in which the code
  is found.
- All C-Sets #C12Qa should be allocated as Invention information (INV).

#### **C-Sets syntax rules:**

- Each C-Set shall contain two or more symbols. Each C-Set shall contain one base symbol from C12Q 1/68, C12Q 1/6804 C12Q 1/6874, C12Q 1/6897 and C12Q 1/70, and at least one subsequent symbol from C12Q 2500/00 C12Q 2565/634.
- Duplicate symbols are not allowed in these C-Sets.
- The order of the subsequent symbols in these C-Sets is not relevant.

#### C-Sets examples:

#C12Qa: Nanopore sequencing is accomplished by measuring changes to an electrical current as a nucleic molecule is passed through a pore. An application discloses an improved method of nanopore sequencing using an immobilized helicase at the pore entrance:

C12Q 1/6869 is given as a base symbol for the method of sequencing

The essential technical features of the inventive method are assigned using orthogonal indexing codes as follows:

- Feature 1: C12Q 2565/631 being a biochannel or pore
- Feature 2: C12Q 2521/543 immobilized enzyme(s)
- Feature 3: C12Q 2521/513 winding/unwinding enzyme, e.g. helicase

These orthogonal indexing codes are selected to describe the essential technical features of the method, and not to capture all features of the method of nanopore sequencing, such as C12Q 2565/607 being a sensor, e.g. electrode.

Complete C-set: (C12Q 1/6869, C12Q 2521/513, C12Q 2521/543, C12Q 2565/631)

#C12Qa: An application discloses an inventive method of nucleic acid quantification using an amplification method with an external standard and a logarithmic regression for determining the initial amount of nucleic acid present:

C12Q 1/6851 is given as a base symbol for the method of quantitative amplification

The following orthogonal indexing codes in C12Q 2500/00 - C12Q 2565/634 are assigned for the essential technical features of the inventive method:

- Feature 1: C12Q 2545/113 with an external standard/control
- Feature 2: C12Q 2537/165 Mathematical modelling

Complete C-set: (C12Q 1/6851, C12Q 2537/165, C12Q 2545/113)

# Nucleic acid analysis using immunogens (immunoassay G01N 33/53)

#### **Definition statement**

This place covers:

Applications characterised by immunological compounds which are used in the analysis of nucleic acids. This group also includes applications characterised by nucleic acids which are used for analysing or detecting proteins and immunogens, e.g. immuno PCR).

#### References

## Limiting references

This place does not cover:

Immunoassay	G01N 33/53
Immunoassay for nucleic acids	G01N 33/5308

#### Informative references

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

Antibodies	C07K 16/00

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## **Glossary of terms**

In this place, the following terms or expressions are used with the meaning indicated:

Immunogens	means immunological compounds such as antibodies and antigens
iiiiiiuiogens	means initiatiological compounds such as antibodies and antigens

## C12Q 1/6806

# Preparing nucleic acids for analysis, e.g. for polymerase chain reaction [PCR] assay (C12Q 1/6804 takes precedence)

## **Definition statement**

This place covers:

All applications which deal with the preparation/modification of nucleic acids in order to use them or prepare them for subsequent analysis (e.g. amplification techniques (PCR), hybridisation techniques, sequencing of nucleic acids). This group also contains applications dealing with the preservation of DNA or RNA samples.

## References

#### Informative references

Extracting or separating nucleic acids from biological samples, e.g. pure	C12N 15/1003
separation or isolation methods; Conditions, buffers or apparatuses	
therefore	

Extracting or separating nucleic acids from biological samples by means of a solid support carrier, e.g. particles, polymers	C12N 15/1006
Extracting or separating nucleic acids from biological samples by chromatography, e.g. electrophoresis, ion-exchange, reverse phase	C12N 15/101
Extracting or separating nucleic acids from biological samples by using magnetic beads	C12N 15/1013
Extracting or separating nucleic acids from biological samples by filtration, e.g. using filters, frits, membranes	C12N 15/1017

See the "Special rules" section of C12Q 1/68

## C12Q 1/6809

# Methods for determination or identification of nucleic acids involving differential detection

#### **Definition statement**

This place covers:

All documents where the invention concerns a method for determining differential expression (RNA level) and comparative genomics (genomic DNA level) and improvements to such methods. However, if the methods disclosed by an application are known, these applications are classified as products based on the use of the products identified.

#### References

#### Informative references

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

The s	creening and making of libraries (e.g. cDNA libraries)	C12N 15/1072
		`

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## C12Q 1/6811

# Selection methods for production or design of target specific oligonucleotides or binding molecules

#### **Definition statement**

This place covers:

The design of primers and probes using enzymatic techniques for obtaining them.

#### References

#### Informative references

Isolating an individual clone by screening libraries	C12N 15/1034
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	04014544007
Screening libraries presented on the surface of microorganisms, e.g. phage display, E. coli display	C12N 15/1037
Ribosome/Polysome display, e.g. SPERT, ARM	C12N 15/1041
Preparation or screening of libraries displayed on scaffold proteins	C12N 15/1044
SELEX	C12N 15/1048
Gene trapping, e.g. exon-, intron-, IRES-, signal sequence-trap cloning, trap vectors	C12N 15/1051
Protein x Protein interaction, e.g. two hybrid selection	C12N 15/1055
Directional evolution of libraries, e.g. evolution of libraries is achieved by mutagenesis and screening or selection of mixed population of organisms	C12N 15/1058
mRNA-Display, e.g. polypeptide and encoding template are connected covalently	C12N 15/1062
Preparation or screening of tagged libraries, e.g. tagged microorganisms by STM-mutagenesis, tagged polynucleotides, gene tags	C12N 15/1065
Template (nucleic acid) mediated chemical library synthesis, e.g. chemical and enzymatical DNA-templated organic molecule synthesis, libraries prepared by non ribosomal polypeptide synthesis (NRPS), DNA/RNA-polymerase mediated polypeptide synthesis	C12N 15/1068
Differential gene expression library synthesis, e.g. subtracted libraries, differential screening	C12N 15/1072
By coupling phenotype to genotype, not provided for in other groups of this group	C12N 15/1075
Screening libraries by altering the phenotype or phenotypic trait of the host	C12N 15/1079
Preparation or screening gene libraries by chromosomal integration of polynucleotide sequences, HR-, site-specific-recombination, transposons, viral vectors	C12N 15/1082
Preparation or screening of expression libraries, e.g. reporter assays	C12N 15/1086
Design, preparation, screening or analysis of libraries using computer algorithms	C12N 15/1089
General methods of preparing gene libraries, not provided for in other subgroups	C12N 15/1093
Phage display	G01N 33/00
Bioinformatics for probe design or probe optimization	G16B 25/20
	-

See the "Special rules" section of C12Q 1/68

# C12Q 1/6813

# **Hybridisation assays**

# **Definition statement**

This place covers:

All applications dealing with hybridisation assays which can not be classified in any of the hybridisation subgroups.

See the "Special rules" section of C12Q 1/68

## C12Q 1/6816

## characterised by the detection means (C12Q 1/6804 takes precedence)

## **Definition statement**

This place covers:

Applications dealing with the detection of hybridisation assays characterised by the detection means.

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## Glossary of terms

In this place, the following terms or expressions are used with the meaning indicated:

Means of detection	the mechanism used to detect the hybridisation of a nucleic acid	
	probe to its nucleic acid target (e.g. labels,)	

## C12Q 1/6818

## involving interaction of two or more labels, e.g. resonant energy transfer

## **Definition statement**

This place covers:

All applications dealing with the detection of hybridisation events using the interaction between the labels as principle.

#### Relationships with other classification places

The use of this detection principle in non-hybridisation based techniques such as nucleic acid amplification in group C12Q 1/6844 or sequencing in group C12Q 1/6869 are not covered by C12Q 1/6818 unless the invention resides in an improvement which has general applicability also for hybridisation assays (for instance an improved Taqman probe). In this case, both C12Q 1/6818 and an amplification or sequencing group can be given.

## Special rules of classification

See the "Special rules" section of C12Q 1/68

#### C12Q 1/682

## Signal amplification

## **Definition statement**

This place covers:

All applications where the detection signal generated in a hybridisation reaction is amplified (for instance the use of branched probes or rolling circle amplification to amplify the hybridisation signal).

## Relationships with other classification places

Amplification of target nucleic acids as such wherein the target amplification results in an increase of signal which is not seen as signal amplification and is not classified in <a href="C12Q 1/682">C12Q 1/682</a>.

Electronic signal amplification is not classified in group C12Q 1/682.

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## C12Q 1/6823

#### Release of bound markers

#### **Definition statement**

This place covers:

All applications wherein the hybridisation detection depends on the physical separation and subsequent detection of a signalling moiety.

## Relationships with other classification places

The use of this detection principle in non-hybridisation based techniques such as nucleic acid amplification in group C12Q 1/6844 or sequencing in group C12Q 1/6869 are not covered by group C12Q 1/6823 unless the invention resides in an improvement which has general applicability also for hybridisation assays. In this case both C12Q 1/6823 and an amplification or sequencing group can be given.

## C12Q 1/6825

## Nucleic acid detection involving sensors

## **Definition statement**

This place covers:

All applications wherein the detection of the hybridisation reaction depends on the electrical or physical properties of the label or of the nucleic acid molecules themselves.

#### References

#### Informative references

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

Sensors wherein the optical detection is important	G01N 21/00
Sensors and electronic devices involving nucleic acids wherein the electrical detection is important	G01N 27/00

## Special rules of classification

## for detection of mutation or polymorphism

#### **Definition statement**

This place covers:

All methods dealing with the detection of polymorphisms using an hybridisation assay and which cannot be classified in group C12Q 1/683. The detection of methylation and splice variants is seen as polymorphism detection and therefore classified in this group if the detection principle is based on an hybridisation assay.

## Relationships with other classification places

The detection of polymorphisms using amplification based techniques is classified in group C12Q 1/6858. The use of allele specific primer extension is covered by group C12Q 1/6858 and not C12Q 1/6827.

See the "Special rules" section of C12Q 1/68

#### References

#### Informative references

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

Sequence identification involving differential detection	C12Q 1/6809
Allele specific amplification; The detection of polymorphisms using amplification based techniques	C12Q 1/6858

#### C12Q 1/6832

## **Enhancement of hybridisation reaction**

#### **Definition statement**

This place covers:

All applications dealing with the enhancement of the binding between a target and its probe, e.g. use of special buffer components, temperatures, probe modifications.

#### References

#### Informative references

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

Sequence identification involving differential detection	C12Q 1/6809
Increasing the specificity or sensitivity of an amplification reaction	C12Q 1/6848
Allele specific amplification	C12Q 1/6858

## Special rules of classification

## Enzymatic or biochemical coupling of nucleic acids to a solid phase

#### **Definition statement**

This place covers:

All applications dealing with the enzymatic and biochemical coupling of nucleic acids to solid surfaces for the use in low throughput assays and the application of those solid surfaces in the subsequent analysis of a nucleic acid.

#### References

#### Informative references

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

Design and fabrication of microarrays (biochips) wherein the invention resides in the synthesis of polypeptides or polynucleotides; Apparatus and devices for combinatorial chemistry or for making molecular arrays.	B01J 19/00
Chemical synthesis or modification of nucleosides, nucleotides or oligonucleotides, chemically linked to other compounds (fluorescent labels)	C07H 21/00-C07H 21/04

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## C12Q 1/6837

## using probe arrays or probe chips (C12Q 1/6874 takes precedence)

## **Definition statement**

This place covers:

All nucleic acid analysis methods which depend on the use of probe arrays (biochips, microarray). If the use of the array is in the context of a method which can be classified in another group of the hybridisation based assays, e.g. C12Q 1/6813, the classifier has to decide based on the relevance of the method to classify the application in either one of these groups or even to classify the application in both groups if necessary. However, if the use is for sequencing then the application is only classified in group C12Q 1/6874.

## References

# Limiting references

This place does not cover:

Involving nucleic acid arrays, e.g. sequencing by hybridisation [SBH]	C12Q 1/6874
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#### Informative references

Design and fabrication of microarrays (biochips) wherein the invention	B01J 19/00
resides in the synthesis of polypeptides or polynucleotides; Apparatus	
and devices for combinatorial chemistry or for making molecular arrays.	

Chemical synthesis or modification of nucleosides, nucleotides or	C07H 21/00-C07H 21/04
oligonucleotides, chemically linked to other compounds (fluorescent	
labels)	

See the "Special rules" section of C12Q 1/68

## C12Q 1/6839

# Triple helix formation or other higher order conformations in hybridisation assays

## **Definition statement**

This place covers:

All methods dealing with the formation of a triple helix DNA conformation. This group also covers other higher order conformations of nucleic acids (quadruplex).

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## C12Q 1/6841

## In situ hybridisation

## **Definition statement**

This place covers:

All applications dealing with methods for the analysis of a nucleic acid in a cell or positionally in a chromosome like Fluorescent In Situ Hybridisation [FISH].

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## C12Q 1/6844

## **Nucleic acid amplification reactions**

## **Definition statement**

This place covers:

All amplification methods which do not belong in any of the amplification groups. Generally, amplification techniques which use a mechanism for amplifying nucleic acids and for which no group exists are classified in group C12Q 1/6844. An example of such an amplification technique is strand displacement amplification [SDA].

## References

## Informative references

Microfluidic systems used for nucleic acid analysis like thermal cyclers (PCR-machines), capillary sequencers	B01L 1/00 - B01L 99/00
Chemical synthesis of oligonucleotides	C07H 21/00

See the "Special rules" section of C12Q 1/68

## C12Q 1/6848

# characterised by the means for preventing contamination or increasing the specificity or sensitivity of an amplification reaction

#### **Definition statement**

This place covers:

Methods for preventing contamination in an amplification reaction such as the use of wax barriers, containers, uracil glycosylase, hot start and nested PCR. In addition, all methods relating to increasing the specificity or sensitivity of an amplification reaction are classified in this group.

This group also covers means for reducing false positive or false negative signals in an amplification reaction.

These include the use of modified nucleotides, e.g. in amplification reactions designed for amplifying GC-rich templates, special buffer components, pH, reaction conditions, etc.

If the method is designed for a specific amplification technique like PCR in group C12Q 1/686, then it is both classified in the specific amplification group, i.e. C12Q 1/686, and in C12Q 1/6848.

#### References

#### Informative references

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

Methods for preventing contamination before an amplification reaction	C12Q 1/6806
Enhancement of hybridisation reactions	C12Q 1/6832

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## C12Q 1/6851

## Quantitative amplification

#### **Definition statement**

This place covers:

Methods for the quantitative amplification of nucleic acids including the use of standards or mathematical models. This group also covers methods (both again enzymatic and mathematical) for determining the amplification efficiency.

#### References

#### Informative references

ICT specially adapted for hybridisation; ICT specially adapted for gene or	G16B 25/00
protein expression	

See the "Special rules" section of C12Q 1/68

## C12Q 1/6853

## using modified primers or templates

## **Definition statement**

This place covers:

Methods using modified primers or templates.

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## C12Q 1/6855

# **Ligating adaptors**

#### **Definition statement**

This place covers:

Methods where the primer or the template is modified by the ligation to an adaptor.

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## C12Q 1/6858

## Allele-specific amplification

#### **Definition statement**

This place covers:

All methods dealing with the detection of polymorphisms using an amplification assay. The detection of methylation and splice variants is seen as polymorphism detection and therefore classified in this group if the detection principle is based on an amplification assay. This includes allele specific primer extension (also when only one dNTP or ddNTP is incorporated using a polymerase).

#### References

#### Informative references

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

Hybridisation based polymorphism detection	C12Q 1/6827
Hybridisation based polymorphism detection involving restriction enzymes	C12Q 1/683
Sequencing	C12Q 1/6869

## Special rules of classification

# Polymerase chain reaction [PCR]

#### **Definition statement**

This place covers:

All applications dealing with PCR and modifications/improvements thereof (e.g. Taqman, multiplex-PCR, and etc.).

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## C12Q 1/6862

# Ligase chain reaction [LCR]

#### **Definition statement**

This place covers:

All applications dealing with LCR and modifications/improvements thereof.

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## C12Q 1/6865

Promoter-based amplification, e.g. nucleic acid sequence amplification [NASBA], self-sustained sequence replication [3SR] or transcription-based amplification system [TAS]

## **Definition statement**

This place covers:

All applications dealing with promoter based amplification and modifications/improvements thereof.

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## **Glossary of terms**

In this place, the following terms or expressions are used with the meaning indicated:

NASBA	Nucleic acid sequence based amplification
3SR	selfsustained sequence replication
TAS	transcription-based amplification system

## Replicase-based amplification, e.g. using Q-beta replicase

#### **Definition statement**

This place covers:

All applications dealing with replicase based amplifications and modifications/improvements thereof.

## Special rules of classification

See the "Special rules" section of C12Q 1/68

### C12Q 1/6869

## **Methods for sequencing**

#### **Definition statement**

This place covers:

All nucleic acid sequencing methods which cannot be classified in the subgroups for sequencing using mass spectrometry, i.e. in group <a href="C12Q 1/6872">C12Q 1/6872</a> and sequencing using solid surfaces, i.e. in group <a href="C12Q 1/6874">C12Q 1/6874</a>. This group also covers methods for sequencing using nanopores and other sequencing systems based on physical properties of nucleic acids, e.g. Atomic Force Microscopy [AFM].

## References

#### Informative references

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

Allele specific primer extension	C12Q 1/6858
Microfluidic systems used for nucleic acid analysis like thermal cyclers (PCR-machines), capillary sequencers	B01L 1/00-B01L 99/00
Apparatus for sequencing using nanopores or nanochannels	G01N 33/48721

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## C12Q 1/6872

## involving mass spectrometry

#### **Definition statement**

This place covers:

All applications dealing with mass spectrometry based sequencing and modifications/improvements thereof.

## Special rules of classification

# involving nucleic acid arrays, e.g. sequencing by hybridisation

#### **Definition statement**

This place covers:

All applications dealing with nucleic acid array based sequencing and modifications/improvements thereof.

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## C12Q 1/6876

# Nucleic acid products used in the analysis of nucleic acids, e.g. primers or probes

#### **Definition statement**

This place covers:

All nucleic acid products used in the analysis of nucleic acids (e.g. primers, probes, controls) which cannot be classified in any of the subgroups <a href="C12Q 1/6879">C12Q 1/6879</a> - <a href="C12Q 1/6895">C12Q 1/6895</a>. If an application relates both to methods and nucleic acid products, than these applications are classified in both the appropriate method and product subgroups.

#### References

#### Informative references

Differential detection	C12Q 1/6809
Polymorphism detection by hybridisation	C12Q 1/6827
Allele specific amplification	C12Q 1/6858
Probes and primers for the detection of viruses and bacteriophages	C12Q 1/70
Virus antigen in a vaccine	A61K 39/12
Modified nucleosides, nucleotides	C07H 21/00
Bacterial and fungal antigens	C07K 14/195- C07K 14/40
Protozoal antigens	C07K 14/44- C07K 14/455
Antibodies	C07K 16/00
Virus, Bacteriophages	C12N 7/00
Bacterial, fungal and protozoan enzymes	C12N 9/00
DNA or RNA fragments; Modified forms thereof	C12N 15/11
Bacterial vectors	C12N 15/70-C12N 15/78
Vectors for fungal cells	C12N 15/80-C12N 15/815
Animal vectors and their preparation	C12N 15/85

See the "Special rules" section of C12Q 1/68

## C12Q 1/6883

## for diseases caused by alterations of genetic material

#### **Definition statement**

This place covers:

All nucleic acid based diagnostic products. Those include both products for detecting the alterations (polymorphisms including methylation and splice variants) of genetic material and for detecting differential expression of a disease gene. If an application also discloses methods for detecting such polymorphisms or differential expression, the classifier should decide based on the relevance of this method to classify the application also in the appropriate method groups, e.g. C12Q 1/6827, C12Q 1/683, C12Q 1/6858, or C12Q 1/6809.

#### References

#### Informative references

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

Primers and probes for cancer assays	C12Q 1/6886
Diagnostic immunoassays	G01N 33/53

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## C12Q 1/6886

## for cancer (immunoassay for cancer G01N 33/574)

#### **Definition statement**

This place covers:

All nucleic acid based cancer diagnostic products.

#### References

#### Limiting references

This place does not cover:

Cancer diagnostic immunoassays	G01N 33/574
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# Special rules of classification

## involving reporter genes operably linked to promoters

## **Definition statement**

This place covers:

All methods which use the detection of reporter genes operably linked to promoters for screening and nucleic acid analysis.

#### References

#### Informative references

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

Preparation or screening of expression libraries, e.g. reporter assays	C12N 15/10
If the screening or the analysis focuses on protein interaction, expression or activity	G01N 33/5008

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## C12Q 1/70

## involving virus or bacteriophage {(immunoassay for viruses G01N 33/56983)}

#### **Definition statement**

This place covers:

All methods which are specifically designed for the analysis of viral nucleic acids or for the analysis of nucleic acids of bacteriophages. (NOTE: According to the hierarchy this subgroup should not be limited to analysis involving nucleic acids. In practice, however, as Immunoassays/protein based Biospecific binding assays for viruses are classified in GO1N, this subgroup is effectively limited to analysis of viral/bacteriophagal nucleic acids). Methods which are generally applicable to nucleic acid analysis should also be classified in the relevant C12Q 1/68 subgroup.

## References

## Limiting references

This place does not cover:

Immunoassay/protein based Biospecific binding assay for viruses	<u>G01N 33/56983</u>

## Informative references

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

Virus antigen in a vaccine	A61K 39/12
Virus	C12N 7/00

## Special rules of classification

# {Specific hybridization probes}

#### **Definition statement**

This place covers:

All probes and primers for the detection and analysis of viruses and bacteriophages not covered by any of the subgroups  $C12Q \frac{1}{703} - C12Q \frac{1}{708}$ .

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## C12Q 1/702

## {for retroviruses}

#### **Definition statement**

This place covers:

Probes and primers for the detection and analysis of retroviruses. Methods specifically designed for retroviruses are covered in C12Q 1/70 and C12Q 1/68 if necessary.

## Special rules of classification

See the "Special rules" section of C12Q 1/68

#### C12Q 1/703

## {Viruses associated with AIDS}

## **Definition statement**

This place covers:

Probes and primers for the detection and analysis of AIDS associated viruses. Methods specifically designed for AIDS associated viruses are covered in <a href="C12Q 1/70">C12Q 1/68</a> if necessary.

## Special rules of classification

See the "Special rules" section of C12Q 1/68

# C12Q 1/705

# {for herpetoviridae, e.g. herpes simplex, varicella zoster}

## **Definition statement**

This place covers:

Probes and primers for the detection and analysis of herpetoviridae. Methods specifically designed for herpetoviridae are covered in C12Q 1/70 and C12Q 1/68 if necessary.

## Special rules of classification

# {for hepatitis}

#### **Definition statement**

This place covers:

Probes and primers for the detection and analysis of hepatitis. Methods specifically designed for hepatitis are covered in C12Q 1/70 and C12Q 1/68 if necessary.

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## C12Q 1/707

# {non-A, non-B Hepatitis, excluding hepatitis D}

#### **Definition statement**

This place covers:

Probes and primers for the detection and analysis of non-A, non-B, and non-D hepatitis. Methods specifically designed for non-A, non-B, and non-D hepatitis are covered in C12Q 1/70 and C12Q 1/68 if necessary.

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## C12Q 1/708

# {for papilloma}

#### **Definition statement**

This place covers:

Probes and primers for the detection and analysis of papilloma. Methods specifically designed for papilloma are covered in C12Q 1/70 and C12Q 1/68 if necessary.

## Special rules of classification

See the "Special rules" section of C12Q 1/68

## C12Q 3/00

Condition responsive control processes (apparatus therefor C12M 1/36; controlling or regulating in general G05)

## **Definition statement**

This place covers:

Processes involving enzymes or microorganisms in which a process parameter is measured and that or another process parameter is varied in response to such measurement.

## C12Q 2304/00

## Chemical means of detecting microorganisms

#### References

#### Informative references

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

O-linked chromogens for determinations of hydrolase enzymes, e.g. glycosidases, phosphatases or esterases	C12Q 2334/00
N-linked chromogens for determinations of peptidases and proteinases	C12Q 2337/00

## C12Q 2500/00

# Analytical methods involving nucleic acids

## Special rules of classification

Indexing codes  $\underline{\text{C12Q }2500/00}$  -  $\underline{\text{C12Q }2565/634}$  are only used as subsequent symbols in C-Sets and are not allocated as single symbols.

#### C-Sets classification:

Indexing codes C12Q 2500/00 - C12Q 2565/634 are used as subsequent symbols in C-Sets #C12Qa, #C12Na and #C12Nb. The detailed information about the C-Sets construction and the associated syntax rules are found in the "Special rules of classification" in C12Q 1/68 for C-Set rule #C12Qa, C12N 15/10 for C-Set rule #C12Na, and C12N 15/64 for C-Set rule #C12Nb.

## **C-Sets searches:**

C-Sets search queries may be made according to C-Set classification rules #C12Qa, #C12Na or #C12Nb, described in C12Q 1/68, C12N 15/10 or C12N 15/64, respectively.

#### C12Q 2521/525

## **Phosphatase**

## Special rules of classification

When the detection is based on the release of pyrophosphate, classification is made in group C12Q 2565/301.

## C12Q 2525/143

## incorporating a promoter sequence

## Special rules of classification

When the promoter-based amplification (e.g. NASBA, 3SR, TAS) is of relevance, classification is made in group  $\underline{\text{C12Q }2531/143}$ .

#### C12Q 2525/185

# incorporating bases where the precise position of the bases in the nucleic acid string is important

## Special rules of classification

Classification in this group is not to be used for 3'-end base.

#### C12Q 2525/186

## incorporating a non-extendable or blocking moiety

## Special rules of classification

When the incorporation is made in the context of the Sanger sequencing method, i.e. oligonucleotide sequencing using primer elongation and dideoxynucleotides as chain terminators, classification is made in group C12Q 2535/101.

## C12Q 2527/00

## Reactions demanding special reaction conditions

#### Special rules of classification

When the reaction requires the presence of a metal/ion, classification is made in group C12Q 2563/137.

## C12Q 2533/10

## the purpose being to increase the length of an oligonucleotide strand

#### Special rules of classification

When the method involves a ligase detection reaction [LDR], classification is made in group C12Q 2561/125.

#### C12Q 2533/101

#### Primer extension

## References

#### Informative references

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

Allele specific primer extension	C12Q 2535/125
Characterised by the capture oligonucleotide acting as a primer	C12Q 2565/537

## C12Q 2533/107

## Probe or oligonucleotide ligation

## **Special rules of classification**

When the ligation is assessed in the context of a ligase chain reaction or of a ligase detection reaction, classification is made in groups C12Q 2531/137 or C12Q 2561/125, respectively.

#### C12Q 2535/139

# Random amplification polymorphism detection [RAPD]

## Special rules of classification

When the reaction is characterized by incorporating arbitrary or random nucleotide sequences, classification is made in group C12Q 2525/179.

## C12Q 2537/137

## a displacement step

## Special rules of classification

When the method relates to strand displacement amplification [SDA], classification is made in group C12Q 2531/119.

## C12Q 2537/149

## Sequential reactions

## Special rules of classification

Classification in this group is not to be used for reactions that are implicitly known to be sequential (e.g. amplification reactions).

## C12Q 2537/155

## **Cyclic reactions**

## Special rules of classification

When the reaction is based on linear amplification, i.e. non exponential, on asymmetric PCR, on PCR, on strand displacement amplification, on rolling circle, on inverse PCR, on ligase chain reaction, on promoter based amplification or on replicase based amplification, classification is made in groups C12Q 2531/101 - C12Q 2531/149, respectively.

#### C12Q 2537/161

## A competitive reaction step

## Special rules of classification

When the reaction step is used in the context of a quantitative measurement with a competitive internal standard/control, classification is made in group C12Q 2545/107.

## C12Q 2537/163

# blocking probe

## Special rules of classification

When an enzyme inhibitor or activator is used in the reaction or when a non-extendable or blocking moiety is used in the reaction, classification is made in groups <a href="C12Q 2527/127">C12Q 2525/186</a>, respectively.

#### C12Q 2545/114

# involving a quantitation step

## Special rules of classification

When the reaction is based on the use of an internal standard/control or on the use of a competitive internal standard/control, or finally on the use of an external standard/control, i.e. control reaction is separated from the test/target reaction, then the classification is made in groups C12Q 2545/101, C12Q 2545/107 or C12Q 2545/113, respectively.

## C12Q 2549/126

## using oligonucleotides as clamps

## Special rules of classification

When reactions leading to the incorporation of a peptide nucleic acid are involved, classification is made in group C12Q 2525/107.

## C12Q 2563/116

# electrical properties of nucleic acids, e.g. impedance, conductivity or resistance

### Special rules of classification

When the label is electroactive, classification is made in group C12Q 2563/113.

## C12Q 2563/119

## the label being proteinic

## Special rules of classification

When the capture moiety is a protein for target oligonucleotides, classification is made in group C12Q 2565/531.

#### C12Q 2563/125

the label being enzymatic, i.e. proteins, and non proteins, such as nucleic acid with enzymatic activity

## Special rules of classification

Classification in this group is to be used when enzymes are used as labels.

## C12Q 2565/543

characterised by the use of two or more capture oligonucleotide primers in concert, e.g. bridge amplification

#### Special rules of classification

When the primers are used in sequential reactions, with the exception of uses for reactions implicitly known to be sequential, e.g. amplification reactions, classification is made in group C12Q 2537/149.

# C12Q 2565/627

# being a mass spectrometer

# **Special rules of classification**

When a mass label is used in nucleic acid detection, classification is made in group C12Q 2563/167.